S. HRG. 100-797, PT. 2

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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## HEARINGS

BEFORE A

## SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

SECOND SESSION

ON

## H.R. 4783

AN ACT MAKING APPROPRIATIONS FOR THE DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION, AND RELATED AGENCIES, FOR THE FISCAL YEAR ENDING SEPTEMBER 30, 1989, AND FOR OTHER PURPOSES

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**Part 2—(Pages 1–1065)**

**Department of Health and Human Services**

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# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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WEDNESDAY, APRIL 20, 1988

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9:30, a.m., in room SD–192, Dirksen Senate Office Building, Hon. Lawton Chiles (chairman) presiding.

Present: Senators Chiles, Weicker, and Domenici.

Also present: Senator Mikulski.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### SOCIAL SECURITY ADMINISTRATION

### STATEMENT OF DORCAS R. HARDY, COMMISSIONER

ACCOMPANIED BY:
DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET
JOHN R. DYER, DEPUTY COMMISSIONER FOR MANAGEMENT

### OPENING REMARKS

Senator CHILES. Our hearing will come to order. We will begin with the testimony from the Social Security Administration to be followed by the Health Care Financing Administration.

The facts of the Social Security budget request are not much different than those that were here last year. Some continued delays in the system modernization but full steam ahead in projected staffing cutbacks that are causing severe morale problems and threatening to undermine the quality and timeliness of service to the public.

Commissioner Dorcas Hardy is here to explain the budget requests, but before her opening remarks, I want to mention a survey she conducted last fall with several thousand Social Security supervisory personnel. Some of the major findings were that less than one-fourth of the supervisors recommended the Social Security Administration as a good place to work. More than one-half contend there is poor morale among their employees. One-third of the employees felt that they rarely left the office with a sense of accomplishment. Only 8 percent thought that the Social Security Administration was a better place to work than a year ago and 1 in 10 believes things will improve, only 1 in 10.

About 3,000 of the 4,964 respondents provided negative comments and I will quote a few. "Morale through this organization is the lowest I have seen it for some years and I have worked here in excess of 20 years." "Downsizing is having a devastating effect on our ability to provide proper service on to our beneficiaries. Promised systems enhancements have not materialized to compensate for loss of manpower." "By loss of people prior to automation, every corner, legal or not, is being cut. In my office I am forced to put telephones on hold as I do not have the people to answer them."

"It is the little items that are no longer being done because there is no time to do them that have always given the employees the self-satisfaction and the pride we once had in our work. That followup telephone call to let the beneficiary know the status of his request, that extra time we spent on interviews explaining the retirement test just one more time to make sure it was understood. Employees are being pushed into becoming impersonal bureaucrats because we must push to meet numerical standards set for us to impress Congress."

There appears to be grave warning signs, despite evidence that key performance indicators remain good, that staffing cuts are creating difficulties that even the most dedicated employees cannot prevent.

Processing times for hearings, particularly appeals of disability cases, continue to increase while staffing decreases. Current reporting of data does not accurately reflect the actual wait time.

One-third of calls in a recent GAO survey experienced difficult access. Combined with the morale problems which appear to be severe and widespread, there appears to be a real danger that the quality of the services to the public could plummet.

Commissioner Hardy, you are certainly to be commended for commissioning such a survey. I hope you will discuss that and your action to deal with this situation.

### SUMMARY OF REQUEST

Ms. **Hardy**. Thank you, Mr. Chairman. Before presenting the other side of the story, I would like to make perhaps a little bit of a different statement before making my formal remarks. With the announcement of your retirement from the Senate this term, I would just like to thank you for your leadership. We have not always seen eye-to-eye, but I believe that you have been fair and you have been candid in your remarks and I think that in our respective capacities, at least mine of the last 7 years and yours over your tenure of the Senate, that we both do attempt to serve the American public to the best of our abilities. You are far from what the Social Security Administration calls normal retirement age or NRA. But I hope that you remember us when you return to Florida, and remember that when you need us, we are only a phone call away and your check will be in the mail on time and in the right amount. We wish you well and we thank you, Mr. Chairman.

I am here to present our 1989 appropriation request.

Senator Chiles. I hope somebody will answer the phone. [Laughter.]

Ms. Hardy. Yes; they will and they do and that is the other side of the story. Everyone needs to know the whole story about Social Security.

We are here to present our 1989 appropriation request. As you are aware, it has several parts: Payments to the Social Security trust funds, special benefits for disabled coal miners and the Supplemental Security Income Program. But our focus today is the $3,775,661,000 for the limitation on administrative expenses which includes $2,745,591,000 for regular salaries and expenses, $762,200,000 for State disability determination services, $220 million for data processing and telecommunications and a contingency reserve of $47,870,000. This represents approximately a 7-percent increase from 1988 to 1989 primarily due to our request for new, not carryover funding for information technology systems.

The Social Security trust fund programs are in solid financial condition, which has been another discussion that has gone on recently on the Hill. Our primary goal has been to deliver the best possible service to all of the American people, whether they are paying in or receiving, and to keep pace with technology and with the expectations of our current and our future customers.

The General Accounting Office surveys that were done in 1984 and in 1986 show that the public gives SSA high marks on quality of service. In June 1987, the HHS inspector general conducted a followup survey with similar positive results and found that 85 percent of SSA's clients rated services as good to very good.

A new survey recently done by the inspector general reinforces previous findings about our beneficiaries' view of our service. Eighty-seven percent of the people who are served rate us good to very good and two-thirds of those individuals prefer using the telephone when they deal with us.

We view service in a very broad context in Social Security including systems and technological improvements, as well as providing the public with options for transacting their business with us.

We have increased the use of telephone service; we have increased the uses of our communications abilities; and, we maintain the option of face-to-face interviews for those people who still prefer that. Overall about 30 percent of our claims are handled by phone, and in some offices, it is as high as 75 percent. It is totally up to the particular area and those beneficiaries how they contact us. For 1989, the budget provides for the implementation of a toll-free nationwide 800 telephone number and for all field offices to continue to offer appointments. Appointments have been very helpful in scheduling workloads and have reduced waiting times and made service more convenient.

We are also working on a project to improve our earnings and benefit information, especially to the workers of today so they understand what Social Security is and what it is not, so they will know what they can expect from Social Security, and so they can help us maintain more accurate earnings records.

We are working with the States as well to issue Social Security numbers for newborns automatically upon request based on birth data and with parental consent. The procedure has been successful in three States and we expect to work with the States to go nationwide.

Our strategic plan has been a focus of your attention and we have tried and, I think, succeeded in refocusing modernization efforts in Social Security. We have put a renewed emphasis on customer service so that what we do in modernization has a direct relationship to what gets paid out or how our customers view us. Our agency's strategic plan supports this new emphasis and is driving the agency in terms of looking where Social Security should be in the year 2000.

We have a much more efficient system of hardware and telecommunications which is supporting improved service to all of our clients. We believe that by the end of 1988 we will have all of our 22,000 terminals installed in our 1,300 offices and in the processing centers to ensure that all of our claims are taken through the modern claims processing.

You have mentioned, and I am sure that it is a subject on your mind, what effect the modernization efforts have upon SSA in terms of staffing. We believe that we have been able to streamline our operations and continue our gradual employment reductions through attrition, through better management, and through procedural and automation improvements. I believe that we can continue to modernize Social Security and improve our service delivery, consistent with the goals and the priorities of our agency, and, at the same time reach our optimum level in terms of staffing.

We now have the planning mechanism in place to continue our tradition of service into the next century. This year we also have tried an initiative working with the Advertising Council to educate the public on how Social Security works and the value of its protection for workers of all ages. Perhaps you have seen our new booklet, "Social Security: How it Works for You."

The ad campaign has been quite successful. We are educating the public about what Social Security is and what it is not. The tag line, I think, speaks for all of us: that Social Security never stops working. Thank you, Mr. Chairman.

### PREPARED STATEMENT

Senator CHILES. Thank you. We will insert your prepared statement in the record and then proceed to the questions.

[The statement follows:]

## STATEMENT OF DORCAS R. HARDY

Mr. Chairman and members of the Committee, I am pleased to be here today to present the fiscal year 1989 appropriation requests of the Social Security Administration (SSA). These requests total $17.2 billion in budget authority. In addition, funds are being requested at this time for fiscal year 1990, consistent with the policies and programs reflected in the fiscal year 1989 budget. The requests for fiscal year 1990 total $17.0 billion.

### Summary of Budget Requests Before the Committee

I would like to summarize the fiscal year 1989 appropriation requests before the Committee.

- $93.6 million for Payments to Social Security Trust Funds. Through this account the trust funds are reimbursed for the costs of certain benefits and administrative expenses chargeable to Federal funds.
- $878.6 million for Special Benefits for Disabled Coal Miners. These funds cover benefit payments and administrative expenses for that portion of the black lung program administered by SSA.
- $12.5 billion for the Supplemental Security Income (SSI) program. This request includes SSI benefits and reimbursement to the Social Security trust funds for the administrative costs of the SSI program.
- $3.8 billion for the Limitation on Administrative Expenses (LAE). This request provides resources needed to administer the old-age and survivors and disability insurance programs and to perform certain administrative functions for the Medicare program. It also includes resources to administer the SSI program and to carry out combined annual wage reporting for Social Security and Internal Revenue Service purposes. The trust funds are reimbursed from the general fund for the administrative costs of the SSI program and for the nontrust fund share of annual wage reporting. The LAE account includes about $2.7 billion for regular salaries and expenses, $762 million for State Disability Determination Services, $220 million for

automatic data processing and telecommunications expenses, and a contingency reserve of $48 million.

## Social Security Trust Funds

Funds to pay benefits from the Old-Age and Survivors Insurance and Disability Insurance Trust Funds (OASDI) are permanently appropriated, and therefore are not part of the budget requests before this Committee. In fiscal year 1989 we expect to make payments of about $206.0 billion to 34.9 million OASI beneficiaries, and payments of $22.4 billion to 4.1 million DI beneficiaries. The fiscal year 1989 budget shows that the trust funds are sound, reflecting the continuing success of the bipartisan agreement reached on Social Security in 1983, which restored the financial integrity of the system into the next century. Under current projections in the President's fiscal year 1989 budget, balances in the OASI and DI trust funds will grow to more than $147 billion by the end of fiscal year 1989.

Administrative expenses remain a small fraction of the overall trust fund operations. For fiscal year 1989, administrative expenses are estimated to be 0.9 percent of anticipated contribution income to the OASI and DI trust funds under current law and 1.0 percent of benefit payments.

## Agency Priorities

With the Social Security program in solid financial condition, our primary goal is to continue to deliver the best possible service to the American people and assure that our service keeps pace with technology and with the expectations and needs of our current and future clients. To this end, SSA is focusing its energies on the following six priorities:

- Maintaining the fiscal integrity of the Social Security trust funds.
- Providing the best service to the public.
- Improving the way SSA manages its programs.

- Using the best and most appropriate technology available to administer our programs.
- Recognizing and supporting the vital role of SSA employees.
- Educating the public and improving public confidence in Social Security.

SSA's budget requests before the Committee reflect the level of resources needed to continue full support for these priorities. The rest of this statement will highlight recent accomplishments toward these goals and initiatives for the future.

## Service to the Public

General Accounting Office surveys done in 1984 and again in 1986 showed that the public gives SSA high marks on quality of service. In June 1987 the HHS Inspector General conducted a followup survey with similar positive results. It found that 85 percent of SSA's clients rate its service as "good to very good." We are committed to maintaining this record.

At SSA we view service in a broad context—emphasizing systems and technological improvements, as well as providing the public with options for transacting business with SSA through the most convenient means. For example:

- We have increased use of telephone service to conduct Social Security business, while maintaining the option of face-to-face interviews for those who prefer it. Over 37 percent of all claims are now handled by telephone. In addition, the budget provides for implementation of a toll-free nationwide "800" telephone number in fiscal year 1989, which will provide the public an enhanced, convenient service option.
- All field offices now offer appointments for interviews and other business, which reduce waiting times and make service more convenient. Field offices also are adjusting their hours to accommodate the needs of the locality, for example, by opening earlier or remaining open later in the evening.
- We are working on a project to improve the earnings and benefit information which SSA provides to the public upon request. This initiative will

deliver a highly desirable service improvement, and will enable SSA to better carry out its responsibility for maintaining accurate earnings records.

- SSA has begun a test in several States of a procedure to assign Social Security numbers to newborns. Parents may choose for SSA to issue a Social Security number for the baby automatically, based on birth data contained on magnetic tape provided by States to SSA. This procedure reduces the burden on parents and SSA for obtaining a Social Security number. The test has been so successful that we plan to work with other States to implement it nationally.
- We have improved millions of Agency notices by rewriting them in more easily understood language and by improving their format and typeface.

## Strategic Plan and Modernization

SSA's budget request for systems reflects a refocusing of SSA's systems modernization efforts, with renewed emphasis on customer service as the guiding principle in all systems activities. In addition, recent publication of the Agency Strategic Plan provides better overall direction for SSA's further modernization efforts and for other major initiatives.

SSA now has a delivery system of efficient hardware and telecommunications equipment which is supporting improved service to our clients. This budget reflects increased emphasis on development of modernized software and design of an efficient data management system, consistent with recommendations from the General Accounting Office and the Congress.

We are continuing modernization of SSA's claims processing system, which provides online data entry, automated processing, and better control of claims. National implementation began in 1987; and as of the end of January 1988, the new system capability was available in nearly 600 of SSA's field offices. By the end of 1988 SSA will have about 22,000 new terminals and related equipment in all 1,300 field offices and in the processing centers. Software for the new system is being implemented in manageable phases, each of which adds new enhancements to the system. The new system will improve productivity, enhance service, and provide more data to employees, allowing for direct and immediate response to claimant inquiries.

Other recent systems accomplishments include:

- o Development of online queries so that field offices have immediate access to certain information in the data files, such as earnings information for making benefit estimates.
- o Improvements to the annual wage reporting process which enabled processing of the bulk of tax year 1986 reports by July 30, 1987, 2 months ahead of the previous year's performance.
- o Improvements to the automated process that credits beneficiaries for additional earnings, which enabled processing those changes earlier than ever. In March 1987 more than 2 million cases were processed, providing those beneficiaries an average monthly increase of $12.40 due to additional earnings. In January 1988 approximately 2.5 million cases were processed to credit 1986 earnings, resulting in average monthly increases of $13.20 for those beneficiaries.
- o Automation of SSI overpayment notices, thereby reducing manual workloads in SSA field offices.

## Human Resources Management

SSA has been able to streamline its operations and continue gradual employment reductions due to management, procedural and automation improvements, which also enhance service to the public. From fiscal year 1984 to fiscal year 1987, SSA reduced its full-time equivalent (FTE) requirements by about 11 percent. Over the next 2 years, fiscal years 1988 and 1989, we expect to reduce FTEs by another 8 percent, based on planned improvements and consistent with the goals and priorities of the Agency. All of these reductions will be accomplished through normal attrition.

Claims modernization, previously mentioned, will contribute to our ability to maintain and improve service, as well as to achieving significant FTE savings in fiscal years 1988 and 1989. Other recent initiatives which improve our work processes, reduce employment requirements and contribute to better service include:

- Increase in the amount of annual wage reports received on magnetic media instead of paper.
- More effective targeting in selection of SSI redeterminations.
- Software improvements to operating systems which reduce the number of unproductive alerts, exceptions and reviews in field offices and processing centers.
- Reductions in overhead and staff/support positions, especially in headquarters. This is due, in part, to a plan established in January 1987 to provide incentives and opportunities for staff/support employees to move into workload operations positions.

We can continue to modernize and improve SSA's service delivery and at the same time reduce staffing requirements. Furthermore, we now have the planning mechanism in place to continue our tradition of service into the next century.

## Public Information

In closing, I want to mention one other recent initiative, which is part of SSA's public education effort. In December 1987 SSA began a major public service advertising campaign through the Advertising Council. The campaign is designed to educate the public on how the Social Security program works and the value of Social Security protection for workers of all ages, and in particular for young workers and their families. It consists of television, radio, newspaper, magazine, transit and outdoor advertisements scheduled for staggered release over a 4-month period. Advertising materials invite people to phone a toll-free number to receive a free booklet, "Social Security: How it Works for You." This campaign is a significant effort toward achieving one of SSA's six priorities, to educate the public about Social Security and improve public confidence in the program.

## Payments to Social Security Trust Funds

The fiscal year (FY) 1989 appropriation request for Payments to Social Security Trust Funds totals $93,631,000 and covers three general fund payments to the Social Security trust funds. Consistent with the policies and programs embodied in the Administration's FY 1989 request, we are requesting $85,275,000 for FY 1990.

Beginning with FY 1988, we no longer request funds in this account to reimburse the trust funds for military service credits for current military personnel. These funds are being requested by the Department of Defense, the Coast Guard, Public Health Service and National Oceanic and Atmospheric Administration so that the total costs related to current military and other uniformed service personnel are more accurately reflected in the budget.

## Special Payments to Certain Uninsured Persons

The request before this Committee includes $42,606,000 in FY 1989 and $34,275,000 in FY 1990 to reimburse the Old-Age and Survivors Insurance Trust Fund for special benefits paid during fiscal years 1987 and 1988 respectively to certain uninsured persons aged 72 years and over. The payments are made to individuals who did not have a chance to work long enough under Social Security to become insured. These beneficiaries, a declining population, were not eligible for regular monthly Social Security benefits, primarily because they retired before enactment of the Social Security Act or before their occupations were covered under Social Security.

The FY 1989 request for Special Payments to Certain Uninsured Persons is $11,948,000 below the FY 1988 appropriation. The population receiving special payments is a closed group of very aged persons which declines annually. As of September 30, 1987, 20,000 persons were receiving benefits chargeable to the general funds under this provision as compared to 26,000 a year earlier.

## Reimbursement for Pension Reform Administrative Costs

Included in this request is a payment of $1,025,000 in fiscal year 1989 and $1,000,000 in fiscal year 1990 to reimburse the Old-Age and Survivors Insurance Trust Fund for the general Federal funds share of the cost of administering pension reform responsibilities assigned to the Social Security Administration under Public Law 93-406, the Pension Reform Act. The reimbursement is for the cost of furnishing information on deferred vested pension rights to pension plan participants or their survivors.

The request for FY 1989 is $281,000 greater than the FY 1988 appropriation, primarily due to an increase in the number of requests for information (the number of requests rose from 1,050 requests in FY 1986 to 2,208 requests in FY 1987). Also, the FY 1989 request will fund upward adjustments to prior years' transfers.

## Unnegotiated Checks

Also included in this request is a payment of $50,000,000 in each fiscal year, 1989 and 1990, to reimburse the trust funds for the value of benefit checks that remain uncashed after 6 months, plus interest. The Social Security Amendments of 1983 provided for reimbursements based upon estimates developed jointly by the Departments of Health and Human Services and Treasury until a system capable of identifying and validating the exact number and amount of uncashed Social Security benefit checks is implemented by the Treasury Department. The Treasury Department is now in the process of validating this system and the actual amounts of uncashed Social Security checks.

## Special Benefits for Disabled Coal Miners

The fiscal year (FY) 1989 appropriation request for Special Benefits for Disabled Coal Miners totals $628,581,000 and is financed from general revenues. This is in addition to the $250,000,000 which Congress provided last year as a FY 1989 advance appropriation to fund first quarter benefit payments, bring the total FY 1989 appropriation to $878,581,000. It includes

$871,901,000 for FY 1989 benefit payments and $6,680,000 for administrative costs. It does not include reimbursable work done for the Department of Labor, which is budgeted for by that agency.

The FY 1989 President's budget includes for congressional consideration, $847,755,000 to be appropriated for FY 1990, which is consistent with the policies and programs embodied in the Administration's FY 1989 request, and an advance appropriation of $203,000,000 for the first quarter of FY 1991.

The year-to-year decrease in appropriation requests is due primarily to the continuing decline in the beneficiary population. The President's budget assumes benefit increases of 2 percent in January 1989 and 3 percent in January 1990, related to projected pay increases for Federal civilian employees.

## Program Authorization

The black lung program is authorized by title IV of the Federal Mine Safety and Health Act of 1977, which provides for payment of monthly cash benefits to coal miners who are totally disabled because of pneumoconiosis, commonly referred to as black lung disease, and to widows and certain other dependents of miners who were entitled to these benefits or whose deaths were due to this disease.

## Responsibility for Administration

The Social Security Administration is responsible for processing and paying claims for miners' benefits filed from December 30, 1969 through June 30, 1973 and claims for survivors benefits filed through December 21, 1973 or within 6 months after the death of a miner or widow already on the beneficiary rolls maintained by SSA. SSA pays benefits and maintains the beneficiary rolls for the lifetime of all persons who filed with SSA during its jurisdiction.

Since June 30, 1973 SSA has continued to take miners' claims--but as an agent of the Department of Labor, which is responsible for adjudication and payment of these claims and which budgets for the benefit payments and administrative costs of the program. Costs incurred by SSA in taking these claims are reimbursed by the Department of Labor.

The beneficiary rolls for which SSA has responsibility will continue to decline gradually in years to come as a result of the death of miners and the death or remarriage of widows. At the midpoint of FY 1989, 236,000 beneficiaries will be receiving monthly benefits. This is a decrease of 18,000 from the 254,000 beneficiaries who will be receiving payments at the midpoint of FY 1988.

## Explanation of Change for FY 1989 Request

We estimate benefit payment obligations to be $875,000,000 in FY 1989—$40,000,000 less than in FY 1988.

The decrease in total benefits is due to a reduction of $56,000,000 for the lower number of black lung beneficiaries, a reduction of $2,000,000 for slightly lower average monthly payments for beneficiaries in current pay, partially offset by an increase of $18,000,000, which results from the effect of the January 1988 and January 1989 benefit increases of 2.0 percent. The FY 1990 request includes $841,000,000 for benefit payments to an average of about 219,000 monthly beneficiaries.

Our budget request of $6,680,000 for FY 1989 black lung administrative expenses is $194,000 higher than the current estimate for FY 1988. The FY 1990 request includes $6,755,000 for black lung administrative expenses.

## Advance Appropriation

The budget request includes an advance appropriation of $203,000,000 for the first quarter of FY 1991. This request ensures that benefit payments will continue without interruption into the next fiscal year.

## Supplemental Security Income

The Supplemental Security Income (SSI) appropriation provides funds through direct cash assistance to eligible aged, blind and disabled recipients to help finance their basic needs. The appropriation request for fiscal year (FY) 1989 is $9,473,953,000 in addition to the $3,000,000,000 already appropriated for the first quarter of FY 1989, bringing the total appropriation to $12,473,953,000. This includes $11,368,000,000 for Federal benefits to aged, blind and disabled recipients; $13,547,000 for beneficiary rehabilitation services; $1,090,131,000 for payments to the trust funds for administrative costs; and $2,275,000 for research and demonstration projects previously funded from the Assistance Payments appropriation.

Consistent with the Administration's policies and programs embodied in the FY 1989 request, we are requesting $12,300,201,000 for FY 1990 and an advance appropriation of $3,234,000,000 for the first quarter of FY 1991.

### Federal Benefit Payments

The SSI program ensures a minimum monthly level of income to eligible aged, blind and disabled individuals. An individual's income, resources and living arrangements are evaluated to determine the actual amount of SSI payment. Payments are delivered through monthly benefit checks.

The average monthly number of SSI recipients of Federal benefits is projected to increase from 4,046,000 in FY 1988 to 4,155,000 in FY 1989, an increase of 109,000. This increase is due to projected growth in the number of blind and disabled SSI recipients, partially offset by a slight decrease in the projected number of aged SSI recipients.

The FY 1989 request for Federal benefit payments is $11,368,000,000 or $29,000,000 less than the FY 1988 level. The decrease is the net result of several factors:

—The FY 1989 request reflects 12 monthly payments compared to 13 monthly payments in FY 1988. The reduction in the number of payments is the principal reason for the reduction in the amount requested; however,

—The decrease is partially offset by:

- o the 4.2 percent cost-of-living increase projected for January 1, 1989; and
- o the projected increase in the number of blind and disabled SSI recipients.

The FY 1990 request includes $11,176,000,000 for Federal benefit payments to an average of 4,268,000 monthly SSI recipients. In FY 1990 there will be 11 monthly payments and the request assumes a 4.0 percent cost-of-living increase for January 1, 1990.

## Beneficiary Rehabilitation Services

SSA provides funds to reimburse vocational rehabilitation agencies for cost beneficial rehabilitations of SSI recipients and for instances of discontinuation of benefits prior to completion of vocational rehabilitation. For FY 1989 we are requesting $13,547,000 for this activity. This includes $11,200,000 for vocational rehabilitation and $2,347,000 for the referral of SSI recipients with drug or alcohol dependency to treatment programs and monitoring their participation in those programs. The FY 1990 request includes $13,638,000 for the Beneficiary Rehabilitation Services activity.

## Payments to the Trust Funds for Administrative Costs

The SSI and Social Security programs are administered on an integrated basis for purposes of economy and efficiency. The Social Security Act authorizes advances from the Social Security trust funds to pay the administrative costs of the SSI program through the Limitation on Administrative Expenses account. The advances are fully repaid from the SSI appropriation. SSA maintains a detailed cost allocation system, which has been audited by the General Accounting Office, to ensure that the trust funds are made whole (with interest, if appropriate) for the administrative expenses of the SSI program. The FY 1989 request for this activity is $1,090,131,000. The FY 1990 request for this activity is $1,110,288,000.

## Research and Demonstration Projects

This activity funds title II and title XVI research and demonstration projects authorized by sections 1110 and 1115 of the Social Security Act. SSA plans to continue its new approach to demonstration and research activity, concentrating on assisting beneficiaries to secure employment. The FY 1989 request for this activity is $2,275,000. The FY 1990 request for this activity is $275,000.

## Advance Appropriation

The budget request includes an advance appropriation of $3,234,000,000 for the first quarter of FY 1991. This request insures that benefit payments will continue without interruption into the next fiscal year.

## Limitation on Administrative Expenses

The Limitation on Administrative Expenses is a request for authority to spend up to $3,775,661,000 in fiscal year (FY) 1989 from the trust funds for administrative expenses of the Social Security Administration (SSA). From this account, SSA pays for administration of the old-age and survivors and disability insurance programs, the supplemental security income (SSI) program for the aged, blind and disabled, Medicare work performed by SSA and certain other work. For reasons of economy and efficiency, SSA has integrated administration of both trust fund and some nontrust fund programs. The Social Security Act authorizes payment of SSI and certain other nontrust fund administrative expenses from this account, with full reimbursement from general funds in other accounts.

Of the new 1989 budget authority requested:

—$1,099 million is for administering the old-age and survivors insurance program,

—$1,277 million is for the disability insurance program,

—$156.7 million is for SSA's Medicare support functions,

—$1,091 million is for administering the SSI program,

—$74.8 million is for processing annual reports of earnings,

—$29.1 million is for annual SSA purchase contract payments on buildings previously constructed under the purchase contract method of financing, and

—$47.9 million is for a contingency reserve.

Included in the first five activities is $220 million in budget authority for automatic data processing and telecommunications activities and $762.2 million for the Disability State Agencies.

## Automatic Data Processing (ADP) and Telecommunications

SSA expects to obligate $220 million in both FY 1988 and FY 1989 for the lease and purchase of automated data processing (ADP) and telecommunications hardware and software, supplies, and contractual services. Although Congress provided "not to exceed $53,040,000" for these activities in FY 1988, SSA expects to fund them primarily from unobligated funds carried over from FY 1987. SSA is using the flexibility provided by this language to make the $53,040,000 available for absorbing the cost of the January 1988 Federal pay raise and other administrative expenses. Because SSA plans to use all of its accumulated unobligated balances in FY 1988 rather than using new budget authority, the FY 1989 request for $220 million in new, no-year authority is to cover the estimated obligations in full.

SSA has reassessed its systems strategy as Congress and the General Accounting Office have recommended. The new systems strategy, reflected in this budget request, places more emphasis on software development, restores customer service as the guiding principle in all systems activities, and improves systems project management.

Some of the major systems-related areas of expenditure planned for FY 1988 and FY 1989 are:

- o Line charges related to voice and data telecommunications including regular telephones, nationwide "800" service, Federal Telecommunications System charges, and data transmission costs.
- o Modernized software applications and a data management system, using increased contractor support.
- o Increased use of telephones for transactions with the public to enable a convenient alternative to walk-in office visits. SSA will purchase replacement equipment for its offices, acquire additional lines and automatic call distribution equipment and implement, in FY 1989, nationwide "800" telephone number service.
- o Office automation through additional microcomputer systems and supporting software acquisitions.

## Disability State Agencies

The budget request includes $762.2 million for the Disability State Agencies in FY 1989. This represents a net increase of $8.2 million, or 1.1 percent, over the FY 1988 operating budget of $754 million. State agency workloads increase by 1 percent during this period, reflecting a workload increase of 26,000 SSI initial claims and appellate cases.

The principal State agency workloads to be processed in FY 1989 are 1,671,000 new claims for disability, 294,000 continuing disability reviews (CDRs), and 560,000 reconsiderations of both new claims and CDRs. Consistent with General Accounting Office recommendations, SSA's plans for processing CDRs place priority on processing the backlog of those cases most likely to show medical improvement.

Improved productivity will result from work simplification efforts, as well as from the resolution of staffing imbalances and the achievement of more uniform productivity. State agencies have made significant productivity improvement, while maintaining high quality disability determinations, from an average production rate of about 168 cases per workyear in FY 1986 to 194 cases in FY 1987. Continued improvement is expected in FY 1988 and FY 1989, to an average production rate of 210 cases per workyear in FY 1989.

Management efforts to obtain and use existing medical records from treating sources will control medical costs by reducing the number of consultative examinations paid for by SSA.

## Federal Staffing

SSA's staffing plans call for continued progress toward the President's productivity improvements goals. The estimates of workyear needs for FY 1988 and FY 1989 are built upon workload experience in FY 1987 and the time it took to process each unit of work. Projections of workyear requirements also take into account the volume of work SSA expects to process, as well as various factors which will affect the time it takes to process the work, including management and procedural changes and automation improvements. To achieve its overall workyear needs, SSA relies on a mix of full-time equivalents (FTEs), nonceiling employment and overtime workyears.

For this account, SSA is requesting 66,305 workyears for FY 1989, a decrease of 3,765 workyears from the FY 1988 level of 70,070 workyears. We plan to use 66,305 workyears in FY 1989 with 65,045 FTEs, 710 workyears of nonceiling employment (principally summer youth employment), and 550 workyears of overtime. In FY 1989 FTEs decrease from the FY 1988 level by 3,341, and overtime and nonceiling workyears decrease by 424 workyears. In both FY 1988 and FY 1989, overtime is estimated to be about 1 percent of total workyears.

This represents the most effective mix of FTEs, overtime and nonceiling employment workyears for FY 1989.

Most of the workyear decrease in FY 1989 will be achieved as SSA realizes the benefits from investments in technological and management improvements. SSA expects additional savings of 2,285 workyears in FY 1989 through management, systems, and procedural changes, most notably from the phase-in of the automated claims-taking process, which will save 1,760 workyears in FY 1989 from the FY 1988 level.

Other factors which will contribute to reduced workyear needs in FY 1989 are:

—Most of the one-time workloads attributable to the recent tax reform (dependent enumeration) and immigration reform legislation will have been processed prior to the beginning of the fiscal year.

—With State cooperation and parental permission, SSA will issue Social Security numbers to newborns, based on birth data contained in magnetic tape provided by States to SSA. This will reduce regular Social Security number workloads which come to SSA's field offices.

These and other changes will help us to realize our goals to process budgeted workloads, maintain our level of service to the public and continue initiatives toward a more streamlined, efficient organization.

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## BIOGRAPHY OF DORCAS R. HARDY

Dorcas R. Hardy was sworn in as the 10th commissioner of Social Security on June 26, 1986, by HHS Secretary Otis R. Bowen, M.D. She was nominated by President Reagan on March 20, 1986, and confirmed by the Senate on June 19, 1986.

As commissioner of Social Security, she is the chief administrator of the nation's Social Security programs — Old Age and Survivors Insurance and Disability Insurance — as well as the Supplemental Security Income program for the needy aged, blind and disabled. These programs combined provide monthly income to over 39 million people at an annual cost of $223 billion.

Ms. Hardy also serves as chairman of President Reagan's Task Force on Legal Equity for Women.

Before becoming the commissioner of Social Security, Ms. Hardy had been HHS assistant secretary for human development services since May 8, 1981. As assistant secretary, she was responsible for administering human services programs of $6 billion for children, youth and families; the elderly, the disabled and Native Americans; and funding to states for social services to help low-income families.

She was born in Newark, N.J., July 18, 1946, and grew up in the Oranges, N.J. Ms. Hardy received her B.A. degree in 1968 from Connecticut College and an M.B.A. from Pepperdine University in 1976. She also completed the Executive Program in Health Policy and Financial Management at Harvard Business School.

Prior to federal service, Ms. Hardy was associate director of the University of Southern California's School of Medicine Center for Health Services Research where she established a multi-disciplinary health and social policy research organization.

From January 1973 to April 1974, Ms. Hardy served as California's assistant secretary for health under then Governor Ronald Reagan. She was executive director of the Health Services Industry Committee of the Cost of Living Council from 1971 to 1973. From April 1970 until June 1971 she was special assistant to the national chairman and director of the White House Conference on Children and Youth. Earlier, she worked as an aide to Senator Clifford P. Case of New Jersey.

Ms. Hardy has authored and co-authored a number of published articles, several of them relating to the automation of hospital information systems and the rights of children.

Ms. Hardy has been the recipient of numerous awards for her outstanding public service including the highest achievement award given by the Council of Jewish Federations and The Tomas Rivera Award given by the National Hispanic University. In addition, she has been recognized by One Church, One Child, the National Committee for Adoption, the North American Council on Adoptable Children, Inc., the National Association of Area Agencies on Aging and the National Humanitarian Award from the Coalition of Hispanic Mental Health and Human Services Organization.

In California, she was vice president of the Junior League of Pasadena, on the board of directors of the Sierra Madre Girl Scouts Council, and All Saints Children's Center. In 1968, she was chosen by the Girl Scouts of U.S.A. to represent the organization in Pakistan. She was cited for her achievements by Who's Who of American Women, 1978 to the present, and Outstanding Young Women of America, 1978 through 1983. In 1985 she became a member of Phi Beta Kappa.

June 26, 1986

## OPENING STATEMENT OF SENATOR WEICKER

Senator CHILES. Senator Weicker, do you have an opening statement?

Senator WEICKER. Thank you very much Mr. Chairman. Once again we are faced with a Social Security budget that proposes drastic cuts in staff positions yet promises increased productivity. It is also a budget that boasts about handling more claims by telephone than ever before. While I certainly support improvements in productivity and efficiency, I continue to be concerned about how we treat our senior citizens other than simply focusing on processing their Social Security checks. I look forward to the testimony today from Commissioner Hardy and the committee's review of the fiscal year 1989 Social Security budget.

But I also look forward to the hearings that focus on funding the research for Alzheimer's disease, geriatric training, and low-income energy assistance. It is all of these Federal programs, including Social Security, that contribute to the quality of life of older Americans.

Commissioner, as the former Assistant Secretary for Human Development Services, you know better than most, the makeup of many of the other senior programs in the Federal budget. I welcome you before the committee this morning and look forward to your explanations regarding the fiscal year 1989 Social Security budget request and proposed staffing cuts.

## SOCIAL SECURITY SURPLUSES

Senator CHILES. Thank you.

Ms. Hardy, last week I offered a sense of the Senate resolution to not count the surplus in Social Security trust funds, which is really a reserve, when calculating the Federal deficit. The growing reserve of Social Security trust funds currently mask the true size of the Federal deficit by $46 billion in fiscal year 1989, and will understate the deficit by $97 billion in 1993, the year that the Gramm-Rudman-Hollings target calls for a zero deficit. Do you agree with the CBO figures I have cited, which show the magnitude by which the surplus of Social Security trust funds currently contribute to achieving the Gramm-Rudman targets?

Ms. HARDY. Yes; I do agree that those numbers show the magnitude of the trust funds' contribution to achieving the Gramm-Rudman targets, Mr. Chairman.

Senator CHILES. Are you concerned that the Federal Government is, in effect, borrowing Social Security trust funds without knowing how we are going to pay them back?

Ms. HARDY. I think that is an issue that continues to get raised by everyone. Historically the trust funds have been invested in Government bonds, which you are well aware, and the Government has always made good on its obligations. We received about $7 billion in interest this year and that will clearly increase as the trust fund reserves increase. I expect that the Government will continue to make good on its obligations.

Senator CHILES. How do you think we can best guarantee that the next generation is going to have the retirement benefits to which they are entitled?

Ms. HARDY. The 1977 and 1983 Social Security amendments which the Congress passed made the system what it is today, switching from a pay-as-you-go system to a partial reserve system. If this is not where we want to go, then clearly we need a legislative package to make changes to the current system. We are now trying to convince the American public that SSA will be there in their future without massive 20 percent, 30 percent, or whatever kinds of payroll taxes. That is why we clearly need to build these reserves.

Senator CHILES. Would you advise that we try to balance the budget without counting the Social Security surplus?

Ms. HARDY. Moving the Social Security trust funds off budget for the purpose of the Gramm-Rudman deficit calculations could certainly come earlier than scheduled under current law. I wouldn't have a problem with that.

### STAFFING LEVELS

Senator CHILES. For each of the last 4 fiscal years, Congress has provided for higher Social Security Administration staffing levels than requested by the President's budget. Each year the administration has failed to comply.

The latest example: in December, conference report language on the continuing resolution provided for 70,345 full-time equivalent positions. I understand you plan to utilize 68,386 full-time equivalent staff. That committee report language doesn't seem to mean much to you. Should we put that in bill language or try to keep those kinds of staffing levels?

The charter pretty well shows what the Appropriations Committee has done, what the request has been and what the actual numbers are and we see that in every instance actual is below what you requested, certainly below what we appropriated.

Ms. HARDY. The actual is below what was requested. The actual is below what the Appropriations Committee put into report language. The actual is what could be achieved within the dollars appropriated.

In addition, I think this is a question of public service and that is what I want to point out to you. From the GAO reports and the inspector general reports, we are clearly the front line public service agency. Our processing times for SSI and retirement and survivors insurance claims have gone down. We do have some areas where we are taking longer than we should, like hearings and appeals. We are restaffing in those areas. But I think the bottom line is service. We think we are doing a good job in terms of service and the American public is saying to us, you are doing a good job.

### LOW AGENCY MORALE

Senator CHILES. Your morale appears to be at an all time low.

Ms. HARDY. Some of our managers are not happy. It is a very challenging time at Social Security. We are in the midst of tremendous change.

Senator CHILES. Doesn't it seem to you that your agency is in danger of losing many of your most talented and dedicated employees and isn't that going to be kind of a devastating thing if that happens?

Ms. HARDY. I do not see that happening, Mr. Chairman. I am about to meet with all the 9,000 managers in Social Security over the next 6 months, and we will talk to each one of them in terms of what their survey comments really mean. It is interesting to note that they are alleging that the morale of the people who work for them is not as good as their own.

Senator CHILES. Can you think of any way that would improve their morale more than announcing a moratorium on staff cuts until you try to get to the bottom of things?

Ms. HARDY. Mr. Chairman, we are still hiring. We are not a frozen agency. We are trying to balance where the work is, with where we put people. This is not a frozen agency. We are making replacements where we need them. It is a question of balance and it is a question of how best to balance, 68,000 people around this country.

Senator CHILES. You are not rehiring anywhere near as fast as you are attriting?

Ms. HARDY. No; but we are not frozen. If you have a need and you are a district manager and you work with your staff and you talk with your regional commissioner, there are full-time equivalents available where the need exists.

### FIELD OFFICE CLOSINGS

Senator CHILES. I understand that you don't intend to close any Social Security field offices as the result of downsizing.

Ms. HARDY. I have made that commitment to you before and we will make that commitment again. We have annual service delivery reviews. We may have 12 to 15 offices a year that either consolidate or downsize but these actions are based on service needs.

Senator CHILES. But even if your entire staff reduction plan is carried out, you are not going to close any field offices.

Ms. HARDY. We will not accelerate the service delivery reviews that we do every year. We do have consolidations and these actions are based on service. I have made the commitment to you before and I make the commitment again, that if we need more staff, we will ask for more staff. Service is what we base our actions on.

### PRIVATIZATION OF THE DISABILITY PROGRAM

Senator CHILES. Senator Weicker.

Senator WEICKER. Thank you, Mr. Chairman. As you know in the early years of this administration, large numbers of eligible SSDI recipients had their Social Security disability payments unfairly terminated. Many of these recipients, upon appeal, were reinstated in the Social Security program. The administration's action caused great concern in the Congress, a concern which I share, and resulted in the enactment of legislation that made clear the terms and procedures under which disability benefits can be terminated.

In light of the past controversies, I note with a measure of suspicion that the SSA budget justification for fiscal year 1989 indicates that you intend to employ a consultant to develop an alternative disability determination plan for using the private sector to perform disability program functions in the event it becomes necessary.

I would like to know exactly what you have in mind here and what is meant by using the private sector in the event it becomes necessary.

Ms. HARDY. I don't know where that came from.

Senator WEICKER. It comes from your own justification.

Ms. HARDY. I know, but I don't have it in front of me. I think what it refers to is the research and demonstration projects that we are doing under the disability program.

First of all, as you are aware, we have resumed the continuing disability review process. We did about 206,000 cases last year and we plan to complete 294,000 cases this year and next year. We have about a 12-percent cessation rate on those continuing disability reviews. What I found when I came to Social Security is that we need some broader ways to get people back to work.

If there is an ability for someone to work, we don't provide much of an incentive in this disability program. The Disability Advisory Council which just submitted its report to Congress, has suggested that we look at different ways to use the private sector rehabilitation community to help rehabilitate people.

We are still using the States. Also, there are demonstration programs that are going on around the country. I don't have the list in front of me but many of the State and local VR organizations have been recipients of those grants which are pilots to see if we can get people rehabilitated and back to work.

Senator WEICKER. I don't feel my question has been answered. This is under the justification of appropriations estimates for the Committee on Appropriations, it is page 133 and the second paragraph it says other major 19—this is consulting services. It says other major 1987 contracts include a child care referral project for SSA employees and a consultant to develop an alternate disability determination plan. And then dropping down to the last sentence in that paragraph, The consultant for the alternate disability plan will develop an implementation plan for using the private sector to perform disability program functions in the event it becomes necessary.

Ms. HARDY. What we do have is the Federal disability determination service that we have put together which gives us the flexibility to take over certain State workloads if necessary. That has some consultants involved with helping us put it together. I think what possibly can be read into this is we want the private sector to take over the disability program. That is not what is happening. That is all I can say to you. We want to use private referral agencies to help us rehabilitate individuals.

[CLERK'S NOTE.—The following material was submitted by the Social Security Administration for the record.]

### CONSULTANT SERVICES CONTRACT FOR THE DISABILITY PROGRAM

The Social Security Administration may under some circumstances be required to assume the disability determination functions of State agencies. The Social Security Act requires that a State's participation in the disability program must be terminated if it substantially fails to follow Federal rules. The act also permits a State to voluntarily terminate all or part of its disability determination function. There may be other circumstances in which the State is unable to manage its disability claims workload and requests assistance from SSA. For example, a catastrophic event may disrupt the State's operation or a court decision may produce a large call of new claims that exceed the State agency's capabilities.

In any circumstances where the State cannot or will not make the disability determinations, SSA must assume that State's workload. However, since SSA does not have the resources to handle the workloads of large or multiple State agencies on more than a very temporary basis, SSA plans to contract out much of any large workloads it assumes to the private sector. Under present law, the disability decision, itself, cannot be contracted out. To facilitate this planning, SSA has contracted with Thomas L. Jacobs and Associates, Inc., a company that makes disability determinations for a large number of private companies. This contractor is to provide a detailed plan that SSA can use to obtain disability casework services from the private sector. Given this plan, SSA will prepare and preclear a model contract document. Then if all or portions of some State agency's disability determination functions must be assumed, anywhere in the country, SSA will quickly adapt the contract requirements to the particular State's workload. The development of this model should both shorten the lengthy procurement process and assure that any contract awarded for work assumed from State programs contains sound requirements that a prviate company can meet.

### RECRUITMENT AND HIRING PROBLEMS

Senator WEICKER. I have other questions for submission of the record, Mr. Chairman.

Senator CHILES. Thank you. Senator Mikulski.

Senator MIKULSKI. Thank you Senator Chiles and I thank you for allowing me to sit on this subcommittee today even though I am not an official member of this particular subcommittee. Social Security is important to the country, administering our largest entitlement program. However, it is also important to Maryland because their headquarters are in Maryland and 16,000 Marylanders are at the Woodlawn facility.

Mr. Chairman, like you, I have been concerned about the deliberate attempt to undermine morale and productivity at Woodlawn through carefully planned staffing reductions and other activities that really gut the feelings of pride that Social Security once had. Mr. Chairman, I am in a unique situation because like you, I am a walking-around Senator, and I don't have to hire a poll to know what my folks are saying and wherever I go, through west Baltimore, either the city or the county, I hear complaints from the people who work at Social Security. Whether it is the accountant who gave up a career in private sector for less money but a pride in offering his service to their community, the first thing they talked to me about was the Roth early retirement bill because they would like to get out of Social Security because they feel hampered in providing accurate data and accurate service.

To the clerical people, they feel that they are placed under relentless, even savage quotas of productivity that even the finest, most dedicated person can't do. They talk about taking work home and living off more Rolaids than anyone could possibly absorb into their system.

Mr. Chairman, in Maryland, we find that if our American military were in the same state of readiness and morale as the Social Security, we would run the risk of being overrun by an outside threat. It is absolutely at the worst low that I have seen in my 12 years in public service. I just wanted to share that with the committee.

It goes to staffing, downsizing, and many other things and if I could, I would just like to pick up on your staffing question with Ms. Hardy.

Ms. Hardy, you said that you don't have a moratorium on staffing but in addition to going to 68,000 for 1988, I understand by 1993, you are going to cut your levels to 58,000, which is a 27-percent cut since 1984. Do you plan to go to 58,000 and how do you expect to recruit people when they think that they are going to be here today and gone tomorrow?

Ms. HARDY. Senator, there is no concept, idea, effort, or anything else to go beyond the current 1990 reductions which represent a 21-percent decrease over the 6-year period.

Senator MIKULSKI. Are you having problems recruiting people to work at Social Security?

Ms. HARDY. No; we are not having problems recruiting people to work at Social Security.

Senator MIKULSKI. Are you having problems retaining people at Social Security?

Ms. HARDY. No; we are not having problems retaining people.

Senator MIKULSKI. Could you submit for the record what has been the number of applicants you have per job, I am very much interested in that, and No. 2, I would be very much interested, for the record, what is the rate of turnover at Social Security.

Ms. HARDY. I would be pleased to.

[The information follows:]

### APPLICATIONS FOR JOBS AT SSA

The Social Security Administration [SSA] continues to have sufficient applicants for vacancies which are filled by outside recruitment.

Based on available data for fiscal year 1984 (January–September 1984), there were 599 candidates for 273 headquarters vacancies. By comparison in the first half of fiscal year 1988, there were 334 candidates for 266 vacancies, as shown in the table which follows:

SSA HEADQUARTERS RECRUITMENT ACTIVITY

| | January–September 1984 | | October 1987–March 1988 | |
|---|---|---|---|---|
| | Number of vacancies | Number of applicants | Number of vacancies | Number of applicants |
| GM–15 | 1 | 3 | | |
| GM–14 | | | | |
| GS–13 | 5 | 7 | | |
| GS–12 | 4 | 43 | 4 | 15 |
| GS–11 | 1 | 36 | | |
| GS–10 | | | | |
| GS–9 | 7 | 70 | 1 | 12 |
| GS–8 | | | | |
| GS–7 | 37 | 113 | 26 | 38 |
| GS–6 | | | 1 | |
| GS–5 | 5 | 12 | 3 | 2 |
| GS–4 | 20 | 44 | 38 | 69 |
| GS–3 | 82 | 86 | 13 | 45 |
| GS–2 | 111 | 185 | 180 | 153 |
| Total | 273 | 599 | 266 | 334 |

The only area where there is now some difficulty is in the recruitment of clericals at the GS–2 level. This is particularly true for typist and data transcriber vacancies. This appears to be a societal problem: that is, lack of interest or skills, rather than an unwillingness to work for SSA.

Although the level of recruitment has diminished in fiscal year 1988 due to downsizing, we have consistently drawn as adequate supply of candidates whenever there have been specific recruitment efforts to fill critical vacancies. For example, in the first half of fiscal year 1988, there have been 280 inquiries for systems positions. Currently, there are 74 eligible candidates in our direct-hire pool for systems positions at GS–9 through GS–15 levels. Additionally, we have 55 applications on file of current and former Federal employees who have expressed interest in systems positions.

Overall, our ability to meet specific recruitment needs has not been adversely affected by our downsizing initiative. Since 1984, there has been an adequate supply of candidates with the right combination of knowledge, skills, and abilities to fill critical vacancies. We expect that this will continue to be the case.

We have also been successful in attracting applicants for jobs in the field. For example, when we advertised to fill 112 vacancies for teleservice representatives to staff up for our 800 number service in Birmingham, AL, we had over 3,600 applicants.

## ATTRITION RATES

The following table shows annual attrition rates (turnover rates) for the last few years for full-time permanent [FTP] employment and part-time employment:

[In percent]

| | Fiscal year— | | | | |
|---|---|---|---|---|---|
| | 1984 | 1985 | 1986 | 1987 | 1988[1] |
| FTP | 6.0 | 6.4 | 6.8 | 9.6 | 8.4 |
| Part time | 15.4 | 15.7 | 15.4 | 15.8 | 13.3 |

[1] The fiscal year 1988 rates are a projection based on 6 months of actual experience.

Attrition occurs for a number of reasons including normal retirements, resignations, discontinued service retirements, and transfers to other agencies.

### SERVICE DELIVERY REVIEWS

Senator MIKULSKI. In terms of downsizing, I would like to just bring up some of the answers to questions I tried to get from your office when Social Security wanted to close an office at the Dunbar Multipurpose Center in east Baltimore, something that has been in operation for a number of years.

We asked what was your criteria for selecting offices to close. We got no answer. The post office has a whole process for determining whether an office should be closed, we are now determining the mechanisms for closing military bases and there seems to be an adequate criteria for that. What then, other than the glib phrase service do you have as criteria for closing?

Ms. HARDY. We have a list of criteria that we would be glad to share with you, as we have with your staff and Senator Sarbanes' staff, in relation to that specific office. It was located 1 mile away from the office into which they are now consolidated.

Senator MIKULSKI. From what we understand in meeting that there is no uniform model. There is no matrix that you apply in terms of number of visits and so on. There seems to be a lack of uniformity and consistency.

Ms. HARDY. I don't quite concur with that. There are different needs in different communities. We have different needs in different parts of the country, but the regional commissioners and our Deputy Commissioner for Operations have criteria that are all looked at when we do service delivery reviews.

Senator MIKULSKI. Do you have minimum standards out of headquarters that you provide for your regional offices?

Ms. HARDY. The service delivery reviews are consistent throughout the country. We look at a number of issues; service, type of population, location, transportation, size, all of these things are taken into consideration.

Senator MIKULSKI. Mr. Chairman, there seems to be a lack of consistency here. When we have been trying to get at this criteria, we have had a difficult time getting consistent standards for the country, or what then is applied regionally.

You represent Florida, a State with a substantial number of elderly citizens. In my State we have pockets of the elderly, so we understand regional and community difference, but I, quite frankly, in dealing with Ms. Hardy's office, have had very difficult time trying to get a consistent standard.

Mr. Chairman, my concern is that in downsizing, you received assurances that no offices would be closed. We thank you for asking that question. But you see we get into downsizing on the basis of service, Mr. Chairman, and I think that is just a code word for closing offices and I would really urge the committee to pursue what criteria will be used for downsizing and consolidation because I think you will find that consolidation is really a closet closing.

Ms. HARDY. Senator, we would be glad to provide that for the record; but clearly, we are going to consolidate offices when transportation is the same to another office that is 1 mile away and the same kind of service can be provided. That has gone on in Social Security, it will continue to go on in Social Security.

[The information follows:]

### CRITERIA FOR CONSOLIDATING OFFICES

The agency policy and procedures for opening, closing, and adjusting service areas for field facilities are contained in the SSA administrative directives systems [ADS] guide which has been in effect since 1980. It includes the minimum criteria for evaluating the viability of new facilities. While rigid numerical criteria do not exist for closing facilities or adjusting service areas, it describes the many factors which should be reviewed and evaluated during the decision process.

The guide has been supplemented by two memoranda issued in 1985. The May 5, 1985, document supplements the basic methodology and discusses the major factors considered in the decision process to ensure we provide the best public service in the most efficient way (workload and related staff size, demographics, and accessibility). The August 15, 1985, memorandum supplements the review and reporting process.

On March 24, 1988, Commissioner Hardy approved changes to the guidelines and delegations for approving facility modifications and service area adjustments.

### SERVICE DELIVERY REVIEWS

Senator MIKULSKI. Mr. Chairman, on that one matter in Baltimore, we just tried to use it to get at a national problem. I found it very interesting, Ms. Hardy, when I was talking to the president of the city council of Baltimore last night where she has been talking to your people in personnel, they said to her, "we can't talk about it until Mikulski comes to the hearing tomorrow with our Social Security Administrator." I don't know what——

Ms. HARDY. Excuse me, Senator. I don't know who is talking here, but I know the Deputy Commissioner of Operations in Social Security has met with the chairman of the city council of Baltimore, with numerous staff from congressional and Senate offices and we are pleased to meet with anyone to explain how we do things, why we do things, how best we can provide service to the Baltimore public.

Senator MIKULSKI. We know that you have been meeting and that is appreciated, but we don't want to stop the telephone meeting Baltimore City Council President Clarke requested because you and I were going to meet today.

Ms. HARDY. We are pleased to meet with anyone in the city of Baltimore.

### ONSITE DAY-CARE CENTERS

Senator MIKULSKI. Mr. Chairman, I have one last question.

As you know, the issue of work force readiness is of great concern to us and one of the things that has been done by the GSA is the attempt to establish onsite day care, particularly where there is a large number of women employees.

Social Security is a significant employer of the female work force. I am told by GSA and the employees at Woodlawn, that you oppose an onsite day care facility. Would you tell us what your position is, rather than what I am told your position is?

Ms. HARDY. With my experience since coming to Social Security and in my previous employment working in the child care area, I believe that all of the studies and the employee surveys demonstrate that what employees are looking for is access to child care, not necessarily having the child right there. We have instituted what we consider a very positive new service; an information and referral service for child care.

I believe all Social Security employees should be treated equitably. With 68,000 people spread across the country in large-, small-, and medium-sized offices, I decided that it would be better to provide employees with access to a phone number where professional child care personnel can refer them to local, certified, licensed day care: preschool, postschool, latchkey, sick care, infant care, all kinds of child care needed for the family whatever the age of the child.

We have a broad referral policy and employees are using this service. They are calling; and, frankly, we do not have the friction between the office with 12 employees with no child care service and a large processing center with onsite child care. I know that when we have taken polls throughout the agency people have suggested that it would be nice if the employer provided child care. I do think that we should provide access but we should not be the provider of child care.

Senator MIKULSKI. Ms. Hardy, I think the fact that you are providing information referral is excellent. I am trying to encourage the establishment of information referral programs nationwide and would welcome your providing information referral, whether you are using the Maryland Locate Program or other services, because I think that is important.

Ms. HARDY. We have our own program dedicated to our own employees nationwide. It is the largest, I think besides IBM, in the country.

Senator MIKULSKI. This is, of course, one of the important tools then that a worker, a mom or dad can have. However, coming back to the onsite day care issue, I asked Constance Horner and GSA to do a feasibility study for onsite day care in certain key agencies, particularly in Maryland. They included NSA, NIH, your agency, and the Naval Academy. Has OPM contacted you about that study?

Ms. HARDY. Not to my knowledge, no, ma'am.

Senator MIKULSKI. Has OPM contacted you as one of the large employers of women in terms of your ideas and recommendations on how we should respond to the day care demands of your workers?

Ms. HARDY. I have not been contacted by Connie Horner to my knowledge. She has not called me. I would be glad to call her.

Senator MIKULSKI. I am going to stop my questions now, but you have obviously put a lot of thought into this and you and I might disagree on some things but I would like to have the benefit of your thinking on what you think we need to be able to do, because it is very hard to ask the private sector to provide day care when I think we should begin to be a model for ourselves and our own workers. We are a major employer in this country.

Ms. HARDY. In the Woodlawn area we have a lot of empty spaces in surrounding private day care and family care facilities. We believe that there are places, good quality, certified, licensed homes available that can be used. But I will take the opportunity to call Connie Horner and see if we can provide input for that survey.

Senator MIKULSKI. And your Secretary of Labor, Ann McLaughin, was also working on this. Mr. Chairman, I have some other questions I would like to submit to the record. You were more than generous in having me here.

Senator CHILES. Senator Domenici.

### DISABILITY PROCESSING TIMES

Senator DOMENICI. Thank you, Mr. Chairman. I, too, have some concerns about both morale and the processing time in the Social Security facilities in my State, and particularly in my home city of Albuquerque.

Reports from my home State indicate that service is suffering in some of the field offices. There is a major press report from a journalist who has been in contact with a number of the people that work there. It indicates that the disability claims that were once handled in 10 days to 2 months in that Albuquerque office are now taking 3 to 4 months. These reports differ from your claims of improved mean processing times which I found on page 109 of your budget justification. Your justification, on page 89, indicates that the field offices are due for some additional reductions of nearly 3,000 more work-years in the fiscal year 1988–89 cycle.

While I support increased efficiency, it is obvious to me that this is not a fund that is without resources to maintain an adequate service to the elderly and for the disabled that come within its jurisdiction.

Is there some specific problem in New Mexico or in Albuquerque, or am I missing something in your statistics? Is there some problem that has developed, perhaps, since the 1987 information that you supplied to us in your budget justification?

Ms. HARDY. There are no specific problems that I am aware of, Senator, but I will share with you two thoughts. One is that, in terms of the disability program, we have increased the number of continuing disability reviews. The process is paper-intensive. We ship folders out of Baltimore and these folders arrive in New Mexico or any of the field offices. Because we are trying to keep the cycle of folders moving so that we can complete the continuing disability reviews and decide whether current beneficiaries should be on or off the disability rolls, there are folders stacking up in field offices. Beneficiaries have to be called and the folder then moves into the State disability determination service. So there is more paper in the field offices at the current time because we are trying to keep that pipeline going and not have our people just sit there and say, well, where is my next folder. Some of the field people are saying to me, "I have all this stuff, this paper here." It is not that it is any more paper in total, but it is more visible in many cases.

I will be meeting with our people from Albuquerque. They are coming into the Dallas regional meeting.

Senator DOMENICI. When will that be?

Ms. HARDY. That will be in early June. One of their concerns is that we have a statewide phone service in New Mexico which has done an extremely good job since 1982 or 1983. As we convert to an 800 phone service nationwide, those employees are concerned about what will happen to them. They will still have a job. There is no question of that. Whether they are answering the phone in Albuquerque is something that may have to be revisited over the next 2 years. There is no question about it, there is tension and concern among the employees because of the changes that are going on.

Senator DOMENICI. I don't want to take a lot of the subcommittee's time on one city's office, but it seems to me that we do deserve an answer as to whether or not your testimony about improvements in the time that it is taking for various claims to be processed are systemwide. I think it would serve a good purpose to pick an office and see if your mean statistics are relevant, and if they are not, to explain why. Maybe you are right; maybe it is just a question of adjusting to the new workload, but if what I am hearing is right, then your national assessment certainly does not necessarily apply to the Albuquerque facility. I would like to have an answer as to why Albuquerque doesn't meet your improved time of maintenance and handling of claims. I think it might be helpful to us, and if you could do that, I would greatly appreciate it.

Ms. HARDY. I would be very pleased to do that, but I would like to remind everyone about the surveys that we are continuing to take about the service that we render to the beneficiaries and to anyone who comes in contact with us. We are getting very high marks. Eighty-seven percent of the people believe that the service that they receive from Social Security is good or very good.

## TOLL-FREE TELEPHONE SERVICE

Senator DOMENICI. I am not adverse to your including that in your response when you evaluate the Albuquerque office. I would like very much for you to give us that so that when we meet with them, we can give them both your explanation and what you say the survey reveals. I think the more relevant the survey is to the area or the more relevant it is statistically, the better purpose it will serve in talking with those who are trying to administer the program.

One last question. With reference to the toll-free 800 number, if people are not getting service under the 800 number, or it takes too long, will they still have the option of contacting their Social Security office in the regular and ordinary manner?

Ms. HARDY. Yes; there will be numbers listed in telephone books around the country that will have an 800 number. As we phase all of this in, the local numbers will still be there and callbacks still will come from the local office. We are trying to provide one central place for information requests, requests for Social Security numbers and all of the public traffic that comes over the phone, giving the customer a better way to talk to Social Security.

Senator DOMENICI. Do you know now how many work-years the 800 lines are going to save in the offices overall, what other savings would accrue from them, and what the budget costs are?

Ms. HARDY. I can supply that for you. Most of the budget costs are in the telecommunications area. We have to upgrade our current teleservice centers anyway and there are 34 of those, so the upgrade will be part of this new initiative.

This is not being done for the work-year savings. It is my view that the beneficiary of today and tomorrow is totally different than the person who came on the rolls in 1945. We are still providing service, in many cases, as if we had that same kind of person. You and I are different than our parents and we have different expectations of Government service. I think the 800 number is just part of that whole view of where we should be in the future.

Senator DOMENICI. It is your position then that the 800 number is not there as a substitute for those senior citizens who feel uncomfortable with it and desire the more personalized service that they have grown accustomed to.

Ms. HARDY. Not at all. We provide options to deal with Social Security. You can call us on the phone, you can write us a letter and you can come see us in an office.

[The information follows:]

### COSTS AND SAVINGS OF TOLL-FREE 800 NUMBER SERVICE

The fiscal year 1989 President's budget includes $28 million in fiscal year 1989 for purchase and installation of equipment and line charges related to the national 800 number service initiative. These costs will be offset to some degree by the current costs for 800 service on a local and statewide basis. There are no work-year savings budgeted. The nationwide 800 number is not designed as a cost-saving measure, but a means of improving the quality of the telephone service we currently provide to the public.

### CONTINGENCY FUND

Senator DOMENICI. My last question has to do with the contingency fund. Outlays for the contingency funds that Congress appropriates for you are not scored in the appropriations process until you spend them. What is your view of the administration's legal requirements for offsetting these estimated outlays if you decide to use the contingency fund?

Ms. HARDY. I have been the only one in Social Security who never wanted a contingency fund. So at least it has come down since I have been here. I would rather come back and say I need more rather than have this line here. As far as the legal requirements, I defer to the budget experts.

Senator Domenici. Can you supply the committee with a table showing, historically since 1981, the contingency fund allowed by appropriations action and how much of it was used?

Ms. Hardy. We have never used any of it while I have been Commissioner, but, yes, we will supply that for you, Senator.

Senator Domenici. I think especially in light of the fiscal constraints under the bipartisan budget summit agreement, Mr. Chairman, the budget impact of these contingency funds take on added importance. Thank you very much.

[The information follows:]

LIMITATION ON ADMINISTRATIVE EXPENSES USE OF CONTINGENCY RESERVE

| Fiscal year | Contingency in appropriation | Contingency apportioned for use | Amount of contingency obligated |
|---|---|---|---|
| 1981 | $80,000,000 | $50,000,000 | $7,384,000 |
| 1982 | 70,000,000 | 70,000,000 | 11,771,000 |
| 1983 | 50,000,000 | 37,823,000 | |
| 1984 | 50,000,000 | | |
| 1985 | 50,000,000 | | |
| 1986 | 138,765,000 | | |
| 1987 | 160,000,000 | | |
| 1988 | 47,870,000 | | |

## MEASUREMENT OF SERVICE TO THE PUBLIC

Senator Chiles. Thank you, sir.

Ms. Hardy, there are many kinds of services to the public that are not being currently measured. Such as how long it takes to answer mail, helping clients replace lost checks, adjusting benefit levels after clients report a change of address and changes in other circumstances.

How can we know that services to the public are not deteriorating if we don't measure some of these items?

Ms. Hardy. Several of those are being measured Mr. Chairman. For example, the adjustment of checks for additional earnings which we call the automated earnings reappraisal operation was done about 2 months sooner this year than last year and that is sooner than the year before. So if a beneficiary has worked, he is entitled to more dollars and he now sees his adjusted Social Security check in March instead of in August or September, as it was a couple years ago. So there are things that are measurable in there. No; I don't have an estimate for you of how long it takes to answer letters. It clearly takes too long in most places, including my office. But I think most of the things that we believe are important to service are being done and are being done in a timely frame.

## ERROR RATES

Senator Chiles. According to GAO the error rate in processing retirement claims has increased about one-third, from 5.9 percent in 1985 to 8.1 percent in 1987. How do we explain this kind of jump in error rate?

Ms. HARDY. With the error rate that they have been talking about, there are two problems. One is the way we count, and, as usual, we seem to get into fusses about how we count. GAO counts errors under $5 and we count errors of $5 and above in terms of trying to get errors fixed.

Second, we do have a problem in reconciling with IRS, discrepancies in reporting earnings that GAO has brought to our attention very loudly and clearly and we are trying to clean it up. This will ensure that you as a worker will have your earnings posted correctly and that the IRS will send us the tapes in a timely fashion so that corrections to the earnings records can be posted sooner. We expect to be caught up by next year with this reconciliation workload for tax years through 1984 and we expect to have a new memorandum of understanding with IRS delineating the reconciliation process for earnings after 1984.

Senator CHILES. It looks like to me what GAO is talking about is not the small under $5, but I think we are talking about basic dollars and basic evidentiary errors and that is the one that has gone from 5.9 percent in 1985 to 8.1 percent in 1987.

Ms. HARDY. I don't have that, Mr. Chairman. I haven't looked at all the GAO reports but I will be glad to look at that one.

Senator CHILES. It is a draft report. We are still looking at it and I presumed that you had it, too. GAO also shows that total errors have grown from 31.5 percent in all old age surveyors insurance claims, that is up 23 percent in fiscal 1985, up from a 23-percent error rate in fiscal year 1985. That again is a one-third increase in the error rate over a 3-year period.

Wouldn't that indicate that maybe your staff cuts and morale problems are beginning to take their toll, we are now seeing this?

Ms. HARDY. Frankly, what that indicates to me is the fact that we have 78 ways to compute a Social Security benefit is ridiculous. The emphasis should be up front on how to simplify this program.

Senator CHILES. But we are talking about, maybe they have a different way but we are measuring apples to apples. If you measured it in 1985 and you add one error rate and you measured in 1987 and that rate has gone up 30 percent, that tells you there is a problem, does it not?

Ms. HARDY. I will be glad to look at it. I have not seen those charts.

### TELEPHONE ACCESS

Senator CHILES. A recent GAO report indicated serious problems with telephone access to Social Security offices, yet it appears that you are moving toward even greater reliance on doing a service by phone. What have you done to ensure callers don't receive constant busy signals or get placed on hold for long periods of time?

Ms. HARDY. We have looked at each of the teleservice centers on a weekly and monthly basis to figure out what the problem is. Is it volume, is it staffing? We have tried to address each of these situations individually.

One of the things that we have done this year is we have processed almost 8 million Social Security numbers because of the Tax Reform Act. We have done that and we have done it well. We now have Social Security numbers for almost everybody in this country and that has clearly caused a lot of the requests that have come into the offices this year. That work level will decrease significantly.

Senator CHILES. Is it a fact that your local offices are expected to meet certain goals to force claimants to conduct their business by phone? Is that one of your goals?

Ms. HARDY. I am not in the business of forcing claimants or beneficiaries to deal with us in one way or the other. We are in the business of trying to provide options to them. We set targets and goals for our offices and we encourage them to make appointments, to have an appointment system, and to have a lot of their traffic done by phone. If somebody comes to the office, they are very welcome.

Senator CHILES. Then you do set targets and goals.

Ms. HARDY. Of course we set targets and goals. We are trying to manage a very large work force, a very large agency serving 38 million beneficiaries who are getting checks on time and in the right amounts. And yes, I do set goals.

Senator CHILES. Would you think that maybe you should look at those goals if you are getting a heck of a lot of people who are getting a busy signal.

Ms. HARDY. Absolutely. I am doing that on a weekly basis. We are doing that on a monthly basis. We have had concerns about the Fort Lauderdale TSC; I have had concerns about some of the west coast teleservice centers; and, we have tried to address them. We have some very antiquated equipment as well and we are in the process of trying to upgrade our whole telecommunications process.

Senator CHILES. What are you doing to ensure that your planned new telephone system will be able to handle the calls at peak calling time?

Ms. HARDY. We have put out a contract that asks the contractor to do that and we will hold them to it and we will have backup processes to do that. We are coming on in a phased mode and I expect that we will be successful.

Senator CHILES. I guess the bottom line, Ms. Hardy, is that you always tell me that you are looking at this and you are addressing it, but GAO says it is kind of getting worse on the telephone.

Ms. HARDY. But Mr. Chairman, GAO surveys and inspector general surveys show that 87 percent of our clients believe service is good or very good.

Senator CHILES. We have not been asking the public about the telephone.

Ms. HARDY. We have been asking the public about the telephone and we have been asking the public if they can get through. We have been measuring that. We have some problems in some areas and we have put more staff on at certain places. We have also given each teleservice representative the tools necessary to do the job. So instead of one computer terminal to two teleservice reps, they each get a computer terminal. They each have their own equipment and they are doing a good job.

## STRATEGIC PLAN

Senator CHILES. Last year you indicated to me that you planned a moratorium on purchase of computer equipment and software pending completion of a revised plan for systems modernization. My understanding while the broad outlines of such a plan are contained in your report on the Social Security long-range plan, the detail of the plan in each component of your agency is still being worked out.

More importantly, the details of this plan and how they relate to new computer expenditures are still being determined. It would appear to me that until this plan is completed, you can't state with certainty exactly how much of the new funds will be needed for computer expenditures in fiscal year 1989, is that correct?

Ms. HARDY. I don't think that is correct, Mr. Chairman. The agency's strategic plan goes from 1988 to the year 2000. I cannot tell you today what we will need in 1999. Those plans that are being developed are going to have to be broad. They are almost all put together. I think what we should be doing is concentrating on 1989 and 1990 as we put together the 1990 budget. I have maintained the commitment to you that we do not have to purchase additional hardware in 1988–89 and we have met that commitment. We are also very concerned that we don't have large carryover balances that you have been concerned about.

Senator CHILES. It would seem that your plan——

Ms. HARDY. We have committed about 60 percent, 65 percent of our automated data processing dollars as of this month in the fiscal year. We have looked to the future and we have asked for $220 million, which is a large chunk, that will show up because there is not expected to be any carryover in 1988. Seventy-five percent of our request for new dollars is for maintenance: for keeping the computer center open and the tapes running, cutting down on these tapes that go halfway to the Moon and back, getting the tapes on disks, and all of the kinds of things that need to be put into place to keep driving our service.

Senator CHILES. It would seem that if your plan is ready before the start of fiscal year 1989, then we ought to sit down and determine how much you are going to need to spend on computers then.

Ms. HARDY. I will be glad to do that. We have met with the GAO. We are meeting with everybody.

Senator CHILES. I am gratified that you have met with GAO on March 9 and April 11 to discuss your plans. My understanding is that those discussions were hands-on meetings and you discussed the details of the analysis before the decisions were made. I hope those kind of sessions can continue throughout the development of your plan. I think they would be helpful to you and helpful to us as we understand it.

Ms. HARDY. Yes, Mr. Chairman.

SOFTWARE DEVELOPMENT

Senator CHILES. Your recent purchase of computer hardware was, to a large extent, justified on the basis of software being available by 1989. Yet, GAO reported last April software to go with your computer modernization is not going to be ready now until the mid-1990's. Now that you have gone through a moratorium on major procurement while reassessing the entire systems modernization effort, when do you expect software development for program benefits to be completed?

Ms. HARDY. The software development for program benefits is a lengthy process. We are behind in some areas but I am still optimistic we can meet the 1990's targets. The biggest problem is converting the programs that we already have and integrating this with the newer software. This takes up a lot of storage space on the hardware.

Senator CHILES. What plans do you have to try to shorten that time necessary to keep the software development?

Ms. HARDY. You could say that three times to all of the staff. We are working real hard on it and the staff is working very hard to shorten the time for software development, but it is a question of quality. We want to make sure that the quality is there.

Senator CHILES. Is there a danger that your hardware is going to be outmoded by the time the software——

Ms. HARDY. There is always that danger, absolutely. There was that danger when we purchased the dumb terminals and the IBM hardware that we have now. But I don't think that with the way these cycles work, we can afford to not do anything. We have to keep moving forward. For example, we expect that our modernized enumeration system using a computer to give people Social Security numbers, will be up later this year.

Senator CHILES. I know this is frustrating to you, Ms. Hardy, I don't mean to say it isn't.

Ms. HARDY. I hear you.

Senator CHILES. But I can tell you, it is sort of mind-boggling to me how, when we see the leaps in technology that are taking place in computers, that we are now talking about the Cray-4 and leaps above that and here we have the agency that has the greatest need next to star wars of anything in the Federal Government for trying to have computer use and we are seeing, as I say, this explosion in race between all of the industrialized nations as to who is going to use the Galleo Marcinite, and who is going into using the nitrogen to cool and as we go into all of the super-conductivity and here we are still talking about trying to replace a system.

Ms. HARDY. You are absolutely correct, Mr. Chairman, and frankly it is worse when Senator Domenici mentioned disability.

If you are disabled, you still get a file folder, a file folder on you that is this high. How do you put all of those medical records and everything into a system? If your lawyer wants to look at your file, you call somebody——

Senator CHILES. Is part of the problem that we are not approaching this the way we are trying to approach using the computers for star wars? We know, when I listened to the number of tasks that will be necessary for the computers to use and trying to strike it three times to enemy missiles as they take off, as they reach the height of their trajectory, as they begin to fall and you know the mind-boggling task and yet we are putting some minds on that and we think that that is something that perhaps is solvable or certain people think it is solvable.

Ms. HARDY. We think we have some very good consultant experts. We have the National Academy of Science, we just signed with them for them to bring in the 30 greatest computer gurus in the world to keep us on the right track, keep looking at us, talking to us and helping us. I have gone to MIT, I have gone to the private sector, I have gone to American Airlines and I dare say American Airlines when they came in, said we——

Ms. HARDY. Senator Mikulski does not get great comfort by saying that you have gone to the airlines. [Laughter.]

Senator MIKULSKI. Is that a crash program, Ms. Hardy? [Laughter.]

Ms. HARDY. I appreciate that, but the reservation system at American Airlines is the largest reservation system and they have problems. That doesn't make it any better and I share the frustrations. I worry about them daily. The question is: How do we do this? How do we do it better than we are doing? Basically the issue is that we have so much data and so many different files to integrate.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. We have other questions that we will submit for the record and we thank you and your people for your appearances here today.

Ms. HARDY. Thank you, Mr. Chairman.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Question: Morale at the Social Security Administration appears to be at an all-time low. Based on the comments you received last fall, the Agency could be in danger of losing many of its most talented and dedicated employees, quitting in frustration and discouragement. A legacy of forcing long-term career employees to abandon the Social Security Administration, having lost pride in their work, seems to be in the making. Don't you think you would dramatically improve morale by announcing a moratorium on further staffing cuts, while you investigate why 9 out of 10 employees believe working conditions will continue to deteriorate?

Answer: No, I do not believe such a moratorium would be helpful. SSA is currently in transition to a work processing environment in which automated systems are replacing labor-intensive, paper-dominated manual operations. It is normal for such transitions to be marked by a period of uncertainty and anxiety among both employees and management. A moratorium on the staffing reductions could complicate morale problems rather than reduce them. Retaining employees to perform work functions that no longer exist due to automation would result in either idle employees or "make-work" projects to keep them busy--neither of these conditions would improve morale.

I do recognize the concerns of SSA's employees. Our workforce is our most valuable asset, and we are committed to easing the adjustment to the new operating environment. I am in the process of conducting a series of conferences around the country to discuss with SSA managers at all levels additional actions we can take to enhance the morale of both employee and managers.

Question: Do you plan to tabulate the 3,000 narrative comments, to see which problems are most frequently raised?

Answer: No, the narrative comments will not be tabulated, but they have been reviewed and are being used as the basis for discussion in our ongoing field managers' conferences.

Question: For each of the last 4 fiscal years, Congress has provided for a higher Social Security Administration staffing level than requested in the President's budget, but each year the Administration failed to comply.

Here's the latest example: In December, conference report language on the continuing resolution provided for 70,345 full-time equivalent positions, but we now understand you plan to utilize only 68,386 full-time equivalent staff. Does Appropriations Committee report language mean nothing to you?

Answer: Although SSA's actual full-time equivalent usage in recent years has been less than the levels recommended by the Congress, we believe that the level of employment at SSA has been appropriate and consistent with the work to be done and with providing good service. This is borne out by General Accounting Office (GAO) surveys conducted in 1984 and 1986, and a 1987 survey performed by the HHS Inspector General--all of which give SSA high marks from the public on the quality of service provided. In addition, due to governmentwide deficit reduction initiatives, the higher FTE levels recommended by Congress in FY 1987 and FY 1988 could not have been funded with the amounts appropriated for administrative expenses.

Question: If you continue to ignore report language, how can you object to bill language setting a floor on staffing cuts?

Answer: I do not believe that the staffing level for an Executive Branch agency should be determined by statute. Moreover, increases in staffing above the levels needed to process expected workloads would not contribute to increased efficiency or effectiveness at SSA. We have made a commitment to ensure that SSA retains its good record of public service. The level of FTEs in SSA's FY 1989 budget request represents the number of FTEs which we believe are needed to process expected workloads and continue to provide good service to the public.

Question: According to GAO, the error rate in processing retirement claims has increased over one-third from 5.9 percent in 1985 to 8.1 percent in 1987. How do you explain this jump in error rates?

Answer: Over the years, SSA has been moving more of the final review and authorization of Retirement and Survivors Insurance (RSI) initial claims to the local district offices. Each time it has been done, error rates have increased temporarily and then returned to lower levels. SSA expected the increase to occur and has been doing extra training and extra evaluation since the change to overcome the problems due to new responsibilities. For the first quarter of calendar year 1988, the error rate dropped to 7.5 percent. While it is true the incidence of inaccurate payments to new beneficiaries went up, the service to all RSI beneficiaries has improved. The amount of error should be seen in the context of our overall stewardship reports. Overpayment accuracy for dollars paid has improved to 99.7 percent, while underpayment accuracy is at an all time high of 99.8 percent--a 20 percent and 45 percent improvement, respectively, between 1985 and 1987.

Question: GAO also shows that total errors have now grown to 31.5 percent of all Old-Age and Survivors Insurance claims--up from a 23 percent error rate in fiscal 1985. This also represents a one-third increase in the error rate over a 3-year period. Aren't you worried that staff cuts and morale problems are beginning to take their toll, with error rates likely to continue rising?

Answer: The review process from which these data are derived measures a great deal more than the accuracy of benefit rates. This process also measures the extent to which operational components are conforming to internal policies and procedures.

Most of the errors were caused by the omission of certain internal procedures. Out of these situations about 1 in 5 results in incorrect benefit rates. The other situations pertain to technical errors which have no effect upon benefit rates.

We believe that the rise in error rates is temporary and that it is unrelated to SSA's downsizing program.

Question: Is there a danger of creating a "faceless bureaucracy," when many senior citizens may feel more comfortable dealing directly with their problems in person?

Answer: No, the 800 number service will not result in a "faceless bureaucracy". The 800 number project will in no way restrict access to personal service or face-to-face contact in our field offices. The public will continue to have the option to visit any of our field offices. However, if they choose to conduct their business by telephone, service will be enhanced by the 800 Number Project.

Question: Last fall, GAO reported that a backlog of 3.5 million employer wage data reports for the years 1978 to 1983 had to be reconciled with IRS tax data to ensure that workers had their earnings properly credited to their Social Security accounts. Several million more reports apparently need to be reconciled for 1984 and subsequent years. Yet you are requesting only 290 workyears for 1989, the same amount budgeted for fiscal 1988, to address this backlog. How many of the 3.5 million unreconciled reports from 1978-1983 will the Social Security Administration resolve with the 290 workyears requested for fiscal 1989?

Answer: In FY 1989, we expect to process the last 500,000 of the 3.5 million backlog cases from the 1978-1983 period.

Question: When will the 1978-1983 backlog be eliminated?

Answer: The backlogged cases for the period 1978-1983 are scheduled to be eliminated by March 1989.

Question: How much of the 1984-1985 backlog (involving over 1 million employer reports) does the Social Security Administration expect to resolve during fiscal year 1989?

Answer: The 1984-1985 backlog contains approximately 1.1 million reports. We expect to resolve about 1 million of these reports during FY 1989 with the resources remaining after we complete the 1978-1983 backlog in March 1989.

Question: Last year, Senate report language directed you to install ergonomic furniture as you install computer terminals. This furniture would allow maximum productivity by employees, while at the same time protecting their health and safety. Is ergonomic furniture being installed simultaneously with the computer terminals?

Answer: Wherever feasible, offices have been scheduled for design visits and furniture installation prior to the installation of computer terminals. However, most computer terminals were delivered and installed in offices before the implementation of the SSA/Federal Prison Industries Interagency Agreement for the purchase of furniture.

To provide some interim accommodation of computer terminals until such time as we are able to install ergonomic (modular/systems) furniture in all SSA field offices, we purchased a variety of "retrofit" devices. These devices consisted of "ergo arms," various sized lazy susans (i.e., turntables) and computer tables which permit ergonomic placement of the terminal and/or keyboard.

In addition, all SSA field offices have been provided ergonomic chairs. These chairs have adjustable height, tilt and relative back-to-seat positioning.

Question: Is lighting also being adjusted to avoid eyestrain?

Answer: We are providing shielded task lighting for each desk with an overhead storage unit to eliminate any shadows cast by the overhead unit and to provide the proper amount of light needed for handling papers and manuals at the desk. Ceiling light fixtures in individual field offices are relocated as needed based on the new office layouts for the furniture. The design contractor prepares what is known as a reflected ceiling plan when appropriate so that lighting changes can be studied and made.

In addition, we issued instructions in the site preparation guide on how to place terminals in relation to windows to reduce glare, including an instruction to procure window shades, blinds or draperies if necessary to reduce glare.

The prevention of eyestrain is addressed further by the following ergonomic design features of the terminal and the keyboard:

- The terminal has a nonglare screen that can be tilted 15 degrees from the vertical position and turned 90 degrees to the right or left to help eliminate reflections on the screen.
- The user can adjust the brightness and contrast on the screen to fit individual needs.
- The keyboard has a matte finish to reduce glare and has a cord attaching it to the terminal that stretches almost 4 feet so that the user can move to a comfortable distance from the screen to reduce eyestrain.

Question: You have indicated that you plan to go ahead with installing a nationwide "800" telephone number to answer calls from clients. The Internal Revenue Service has instituted a similar procedure. Unfortunately, studies have shown that a high percentage of the answers provided by the IRS to 800 number callers are wrong.

During the past few years, in major metropolitan areas, you have switched from having clients call local Social Security offices to having them call one central number for the whole area. Have you done any testing to see whether the accuracy of the answers given to callers of the central number is worse than the accuracy of answers given to callers of local offices?

Answer: We have an ongoing process of assessing the service provided in our teleservice centers. Supervisory employees observe the accuracy, courtesy and completeness of a sample of calls continuously. Over 95 percent of the calls we assess are fully satisfactory in all respects. The GAO August 1986 report on SSA accessibility also reported that it found SSA provided accurate answers in over 95 percent of its telephone inquiries. We do not have comparative information, however, for the service provided by local offices.

Question: Don't you think it is imprudent to move to a single nationwide telephone number when you have no idea whether the move to city-wide numbers hurt the accuracy of answers to telephone callers?

Answer: We believe that beyond the service benefits, having a nationwide telephone number poses a distinct advantage to the Agency from a measurement perspective. SSA will be better able to monitor and determine its telephone accessibility and information accuracy to its entire constituency when this service is provided through a unified telephone system.

Question: In last year's hearing, I expressed my concerns about the years of false starts and delays in carrying out a computer modernization plan that was supposed to be completed by now. Since that time, you imposed a moratorium while you reassessed systems modernization, and on April 7 you sent me a status report on efforts to refocus systems modernization activities. For the benefit of all Committee members, please summarize how systems modernization efforts have been refocused to improve the quality of services to the public. Is it true that you now contemplate a new 5-year modernization plan, that would be annually updated, and thus never really completed?

Answer: Systems planning at SSA is guided by the Agency Strategic Plan (ASP). The ASP is a 12-year plan which charts SSA's course from now until the year 2000. Within the context of the ASP, various subplans are being developed to apportion the Plan into manageable pieces. Broadly speaking, we are developing Tactical and Operational Plans for each of the major projects identified in the ASP. The Tactical Plans describe the next 5 years of activity in a particular area. The Operational Plans provide a more detailed accounting of the first 2 years of each tactical plan. The ASP and the associated Tactical and Operational Plans will be updated annually as part of SSA's ongoing strategic planning. The Systems Modernization Plan has become part of the ASP and will continue to be monitored. SSA is approaching the completion of the original Systems Modernization Plan, but as in any endeavor such as the extensive computer modernization we have undertaken, there will always be room for improvements and significant upgrades.

Systems refocusing was developed to accomplish four things:

1. Better overall direction of the modernization;
2. Place a renewed emphasis on customer service;
3. Place an increased focus on software; and,
4. Better manage the modernization effort.

Better overall direction means that SSA now has an Agency Strategic Plan to provide guidance for all SSA planning activities, including systems planning.

The renewed emphasis on customer service means simply that we will focus our efforts on modernization projects which have real and tangible results in terms of service delivery improvements. Some examples of current projects are:

- o The expansion of options for service by phone.
- o The "enumeration at birth" initiative.
- o The new improved earnings and benefit statements.

These all provide a new service or a significant improvement to an existing service. They reflect SSA's commitment to use improved service delivery as the universal guidepost in all future systems decisions.

An increased focus on software is an acknowledgement that this is the area where we still have the most work to do. Putting increased focus on the software area means both making better use of existing software and continuing work on developing new software. Some of the key software projects are as follows:

- o Specification of software standards in SSA's Software Engineering Technology Manual, and the use of these standards has been mandated.

- o An outside independent review of the overall data base strategy has been conducted to assess SSA's basic approach. In addition, we have begun a disciplined exercise in technical data modeling to define SSA's long-term data base needs.

- o The specification of SSA's Target Physical Architecture for Software has been completed. This is the initial blueprint of what SSA's systems will look like in the future.

- The Modernized Claims System is already in operation in its initial capabilities. In FY 1988, the first version of our modernized enumeration software will be released.

Better management entails improving four key areas:

(1) More careful management of the systems budget, allocating our resources in a manner consistent with our systems priorities. This means shifting resources from hardware to systems analysis and software. It also means managing projects and managing budgets so that the two achieve a closer fit. In particular, SSA pledged that there will be no Information Technology Systems (ITS) budget carryover into FY 1989.

(2) Establishment of a Systems Review Board which oversees major ADP procurements.

(3) Consolidating the systems functions with the operations functions to improve the coordination between Systems and Operations and to emphasize, yet again, the orientation to bottom-line customer service.

(4) Strengthening of project management and integration--utilizing the services of an outside integration contractor; implementing automated project management tools; improving reporting mechanisms and improving the documentation of important project decisions.

Question: You have indicated that you intend to have no carryover in the computer account for fiscal year 1988. This is an important goal that I have advocated and I applaud your attention to it.

I understand that managerial personnel have been informed that their merit pay and other performance evaluations are dependent upon no computer money carryover in the areas under their control. Although this is reassuring in one respect, it is troubling in another. We have received anecdotal evidence that managers are spending money, whether they need to or not, in order to ensure that they have no carryover at the end of the year. Although I do not know for sure whether this anecdotal evidence is true, it seems reasonable to assume that some managers will spend money unnecessarily if their merit pay rating depends on it.

Don't you think that this type of merit pay rating system encourages waste, even though it eliminates carryover?

Answer: Merit pay performance plans establish goals and determine evaluations for SSA executives. Providing accurate and timely tracking of projects is a specific item in several performance plans because we do expect managers to meet the goals in SSA's systems plans. We are not evaluating managers' performance based on their ability to spend money. I strongly agree that spending for the sake of avoiding carryover money would not be an efficient use of resources and not in the best interests of SSA's clients nor the integrity of the trust funds. What you understand is, indeed, anecdotal. We have constructed a tight, careful systems budget which does not provide for any carryover into 1989, and assuming no significant delays in the procurement process, we expect to meet that target.

In FY 1989, we plan to spend all of the money earmarked for ITS in our FY 1989 request. In order to accomplish our systems budget plan without any wasteful spending, SSA has established a process that will apply more discipline, documentation and accountability in the management of this budget. SSA's Chief Financial Officer will track systems plans on a project-by-project basis, report to me monthly on the status of these projects and ensure the accomplishment of the budget plans.

Question: Your budget proposes further staff cuts of 3,765 workyears, but fails to clearly identify how these cuts will be made, program by program. Can you list and explain all the proposed fiscal 1989 staffing changes?

Answer: SSA's budget justification lists major management, procedural and systems improvements, which are expected to save 2,285 workyears in FY 1989 from the FY 1988 level. These workyear savings are the result of SSA's continuing efforts to automate work, increase productivity and streamline operations. The most significant single initiative included in that group is the phase-in of a modernized, automated claims-taking system. The remaining net decrease of 1,480 workyears in FY 1989 is due to several key factors:

- o Overall workload volumes decrease primarily as a result of the return of the Social Security number workload to a more normal level following the effects of implementing tax reform and immigration reform legislation in FY 1987 and FY 1988 (-561 workyears).

- o Continued improvements in the ratio between operations support workyears (e.g., case control and supervision) and direct processing workyears are expected, thus, reducing workyear needs (-480 workyears).

- o Reductions in staff/support workyears are scheduled to continue (-439 workyears).

Question: How much more staff will you need to beef up priority areas mentioned in your budget, such as: improving earnings statements; expanding telephone services; and reducing the backlog of disability hearings?

Answer: The budget provides additional resources for implementation of priority initiatives. For example:

- o The FY 1989 estimates include 416 workyears related to SSA's initiative to provide improved earnings statement information to the public upon request. These resources are for processing an increased number of earnings statement requests and for resolving subsequent earnings-related problems.

- The budget includes 290 workyears in each year, FY 1988 and FY 1989, for reconciliation of wage and tax data reported annually to SSA with data reported to IRS.
- The budget includes 1,333 workyears in FY 1988 and 268 workyears in FY 1989 for implementation of tax reform and immigration reform legislation. This is primarily for issuance of new or duplicate Social Security number cards to children age 5 or older who are claimed as dependents on Federal tax returns and to certain aliens who are eligible for residency status.

In addition, the budget provides resources for expanded use of telephone service to conduct Social Security business, including implementation of a plan to provide nationwide toll-free "800" number service. Although increased use of the telephone will shift some budgeted workload resources from one location to another, we have also budgeted additional resources to implement this initiative.

The budget also provides additional resources to process hearing workloads. The following table shows the budget assumptions regarding the volume of hearings to be processed in FY 1988 and FY 1989 and the workyears to be expended in SSA's Office of Hearings and Appeals on this workload:

| | FY 1987 Actual | FY 1988 Estimate | FY 1989 Estimate |
|---|---|---|---|
| Hearings Processed......... | 247,138 | 286,000 | 294,000 |
| OHA Workyears for Processing Hearings....... | 3,424 | 3,532 | 3,645 |

Question: Processing time for disability hearings has continued to increase to an average of 222 days for a recent period, up 29 percent since fiscal 1986 when the average was 172 days. What additional resources are needed to reduce the processing time during 1989, and can you tell us realistically how much you will lower the processing time with the additional resources?

Answer: Processing time is derived by measuring the elapsed time from the date the request for hearing is filed to the date a decision is issued. It is not measured from the date the claim file is received by the hearing office and the request is ready to be worked. Average processing time is established by dividing the total time elapsed for all cases processed during any given month by the number of cases processed. Because processing time is measured only after cases are released, an increase in average processing time may not necessarily reflect the overall performance of the Agency. In fact, an increase in average processing time may simply reflect increased productivity in impacted areas and may reflect greater agency responsiveness in processing its oldest cases. It is, perhaps, an anomaly that average processing time is driven upward by processing the oldest cases first; conversely, average processing time will immediately decline by processing the newest cases first. For this reason, a better indicator of Agency performance is the average age of the pending workload.

Nonetheless, increases which have occurred in average case processing times at the hearing level are the result of substantial increases in the volume of requests for hearings since FY 1986. Between fiscal years 1986 and 1987, hearing receipts increased by 48,000 (20 percent), from approximately 230,000 cases to approximately 278,000 cases. We have budgeted for 266,000 hearing receipts in FY 1988, in addition to the Part B Medicare workloads.

When SSA first began to experience these increased workloads, hearing level productivity, measured in terms of dispositions per administrative law judge (ALJ), was at its lowest point in 10 years--23 cases per ALJ per month. In large part, this reduced level of productivity was attributable to low receipts resulting from the Secretary's moratorium on processing certain types of disability cases pending implementation of the 1984 Disability Benefits Reform Act.

Implementation of the Disability Benefits Reform Act, along with other events such as the earlier economic downturn in certain areas of the country, caused receipts to begin climbing sharply in late 1986. At that time, the Agency initiated a number of actions designed to increase hearing level productivity. As a result, the number of total dispositions rose by over 12 percent from FY 1986 (220,313) to FY 1987 (247,138). Based on hearing level performance so far this fiscal year and the planned addition of 28 new ALJs in June 1988, we project total annual dispositions of approximately 286,000 cases, nearly 15 percent above the FY 1987 level. In FY 1986, with over 700 ALJs on board, the per ALJ disposition rate was 27 cases per month. In FY 1987 there were 666 ALJs on board with a productivity rate of 31 dispositions per month. There are currently 644 ALJs on board, and productivity in the first 7 months of FY 1988 has averaged over 36 cases per ALJ per month.

The recent increases in the volume of our dispositions has enabled us to serve many more claimants than would have been possible at the previous rate, and to do so with fewer ALJs. In short, both aggregate dispositions and individual productivity have improved.

Even with additional resources, hearing level performance statistics will not reflect any significant reduction in average processing time until the goal of reducing the percentage of old cases (from the March 1988 level of 11.8 percent of pending to 5.8 percent) is achieved. However, the more important performance measure, the average age of the pending workload, will decrease. In fact, since January 1988, when we began emphasizing processing older cases, the average age of pending cases has decreased from 150 to 144 days. We expect greater reductions as we continue to concentrate on these cases.

In sum, we believe that we are making good progress in reducing the time claimants must wait for their hearings and decisions, even though that progress may not be apparent from processing time statistics. We are utilizing our current resources well and anticipate that continued emphasis on improving hearing level performance through a variety of initiatives will result in a collateral improvement in our capacity for providing effective public service. Some of the activities we have undertaken this fiscal year to achieve our performance goals are summarized below:

- We are concentrating on processing older cases to completion.

- We have a continuing program whereby we attempt to balance resources and workloads in the local offices. For example, we may send ALJs from offices with lighter workloads to offices with heavy workloads to hear and decide a 1- or 2-week docket of cases. If the problem is not one of ALJ availability, we may send cases to be prepared or decisions to be drafted or typed from one office to another or, in the case of decision typing, send cases from a hearing office to 1 of the 4 word processing centers.

- Although we expect to hire only limited numbers of new ALJs during the remainder of FY 1988 and during FY 1989, we have streamlined the recruitment process so that we can hire on a more frequent basis and, thus, address hearing office needs more quickly. We recently received permission from Office of Personnel Management to begin hiring retired Social Security ALJs to fill critical hearing office needs on an immediate basis.

- We have pinpointed those areas of the country which need additional assistance. For instance, the Dallas Region has experienced especially heavy workloads during the last 2 years, and we are currently providing additional support staff and ALJs, both on a permanent and temporary basis, to assist those hearing offices.

- We are introducing personal computers into our hearing offices to provide additional support in processing and tracking cases.

- Because processing delays tend to be a significant problem in only a minority of hearing offices, we will be working individually with the 44 offices having the highest average processing times to isolate and remove case processing impediments.

Question: What do you consider a reasonable processing time for hearings?

Answer: Again, although we monitor average case processing times for hearing level cases, we believe there are other, more accurate means of measuring the effectiveness of the service we render. In general, processing times are unreliable indicators of performance because they do not accurately reflect Agency efforts to provide the best possible service to claimants on a nationwide basis. Failure to process older cases to completion actually results in a better short-term average processing time, while processing the older cases causes an increase in the average time. Conversely, the age of pending cases accurately reflects our efforts to process older cases while, at the same time, providing no incentive for allowing cases to age. Thus, the use of average processing time as a solitary performance measure can serve as a disincentive to improved public service. The Agency has, therefore, not considered what might constitute a "reasonable processing time."

Rather than focusing on processing times, we have concentrated on reducing the size and age of the pending workload. We are projecting that our increased productivity will enable us to keep pace with receipts for this fiscal year. (We are projecting receipts of approximately 278,000 and dispositions of approximately 286,000.) Moreover, by concentrating on aged cases, we are attacking the fundamental problem you identified--the length of time before a claimant receives a hearing decision. Our incentives to focus resources where they are critically needed are also paying dividends. In examining our processing time, we have found that the average processing time is substantially higher in the lower one-third of our hearing offices than in the remaining two-thirds. For example, in March the processing time was 271 days in the lower one-third of our hearing field offices; by contrast, the average processing time was 194 days in the remaining offices (two-thirds). This, too, is indicative that we do not have a national problem with processing times. The problem is localized in those offices which have been most heavily impacted by increased receipts. By addressing the needs of the offices most heavily impacted, we are able to provide service to those claimants who have been waiting the longest time for a hearing and decision.

SSA is also making other efforts to reduce the time it takes for a claimant to have his or her hearing. Some of these initiatives are internal to the Agency while others require the cooperation of claimants and their representatives. For example, SSA components are working closely with one another to reduce the time it takes for the hearing office to receive a claim file after a request for hearing has been filed. We are also, working to reduce postponements and continuances and are encouraging claimants and representatives to submit evidence at the earliest possible time rather than waiting to submit additional evidence after the hearing.

In a recent memorandum to the Regional Chief ALJs, the Chief ALJ established a goal to increase to 85 percent the rate of hearings held to hearings scheduled and instructed the regional hearing offices to work with individual offices in which the ratio is 80 percent or less. The memorandum also discussed a number of strategies for reducing postponement delays, including calling representatives and claimants prior to scheduling the hearing; denying requests for postponement to obtain additional evidence when the evidence can be obtained after the hearing is held; immediate rescheduling of the hearing when postponement is granted; and clearly advising representatives of their obligations with respect to their appearance at SSA hearings. There is evidence that we are making some progress in this area--In April 1988, the ratio of hearings held to hearings scheduled was 83 percent, with two regions exceeding the 85 percent goal and another five achieving ratios of 80 percent or greater. We believe that the initiatives we have undertaken will result in a reduction of the most important performance indicator--the average age of pending cases.

We have set a goal of reducing the proportion of pending cases which are 270 days old or older from the current level of 11.6 percent to 5.8 percent. A natural result of achieving this goal will be a reduction in the overall age of pending cases.

In sum, there are many factors and events which influence processing times, and it would be difficult to establish a standard considered "reasonable." However, SSA is working on a number of fronts to eliminate delays in the hearing level claims process and expects to achieve significant reductions in case processing delays by the end of the fiscal year.

Question: In many Social Security offices, clients take a number and wait to be called, but you apparently don't start counting "wait time" until they see a receptionist. Do you have any idea how long clients must wait to talk to a receptionist, even if they have come in for a prearranged appointment?

Answer: That is correct. We do not measure the time elapsing between the moment of entry and the receptionist interview. A special study, completed in August 1986 and reported to Congress in January 1987, indicated that 41 percent of Social Security office visitors were immediately greeted by the receptionist. For those who did wait, the average pre-receptionist time was 8.8 minutes. Persons with prearranged appointments are generally called at the scheduled time. The overall average time before seeing a receptionist was 5.2 minutes.

Question: Do you believe you get an accurate measurement of "wait time" if local office staff know exactly when the survey is being taken?

Answer: Although there have been concerns about the accuracy of the data, generally our study results are consistent with the experience that the public has reported to GAO and the Inspector General. Waiting times are low.

Question: Do you plan to keep separate statistics on "wait-times" for walk-in traffic, instead of averaging in zero wait-times for those with appointments?

Answer: No, we do not plan to expand our measurement of waiting times. In fact, because our measures show that waiting times are low and the public has a high opinion of our service, we see a declining need to continue to invest resources in the extensive measurement of waiting times. We are considering alternative methods for assuring ourselves that the public is being served promptly in our field offices.

Question: How do you measure how long people have to wait before they receive an appointment?

Answer: Time elapsing between the scheduling of an appointment and the actual appointment is not measured as an indicator of service. One reason for our appointment service is to determine a convenient time for the public to complete their business with us. If the most convenient time is the next day or a week later, we believe both represent timely action. However, we do attempt to keep elapsed time from contact to appointment short.

Question: Your budget proposes to cut 52 staff [workyears] from wage reporting activities, even though GAO has reported a huge backlog of wage reports that have not been reconciled with IRS data. Rather than cut 52 staff [workyears], why don't you use them to reduce the unresolved wage report backlog?

Answer: The GAO report correctly noted that the backlog occurred as a result of differences between IRS and SSA as to who had responsibility for processing these cases--not the adequacy of SSA workyear or FTE levels. While we would like to further expedite the resolution of SSA/IRS wage report discrepancies, the use of the additional 52 workyears in FY 1989 would not help us complete the process any sooner. We are dependent on responses from employers for the work we process. The 290 workyears reflected in the FY 1989 request is the level that we would need in order to process the responses we expect to receive.

We have reached a proposed agreement with IRS which spells out the responsibilities of the two agencies in resolving the discrepancies. I signed a Memorandum of Understanding to this effect on April 14, 1988, and sent it to the IRS. As of May 25, 1988, the IRS Commissioner has not signed the agreement.

Question: Your budget document indicates you plan to spend the entire $220 million requested for automatic data processing and telecommunications before the end of fiscal year 1989. Why, then, are you requesting bill language to let these funds "remain available until expended"?

Answer: It is our intent to spend the entire $220 million in FY 1989. The bill language that allows these funds to remain available until expended provides SSA the flexibility to deal with unforeseen delays in the procurement process. Procurement in the telecommunciations area can be quite lengthy, especially if protests are filed by unsuccessful bidders. We would do well to have flexible funding mechanisms in place in the event this or other kinds of uncontrollable delays occur.

Question: Would you object to making these funds available only for fiscal 1989, as is the case with the rest of Social Security Administration funding?

Answer: For the reasons I have stated, I prefer the language contained in our appropriation request.

Question: How many earnings records of persons coming under the recent immigration legislation have been identified and corrected?

Answer: We do not distinguish earnings record corrections requested by persons affected by the immigration legislation from any other requests for record correction.

Question: Isn't it true that your own internal documents indicate it would take 11,000 workyears to straighten out earnings discrepancies for these new citizens?

Answer: The 11,000 workyear estimate went along with an estimate of 2 million earnings discrepancies--a worse case possibility. This was one of many scenarios we considered when trying to assess the impact of the Immigration Reform and Control Act. We budgeted for our best estimate of 34,000 total earnings discrepancies in FY 1988 and in FY 1989; actual experience indicates the number may be even lower.

Question: Rather than merely measuring the amount of time it took to process a claim, isn't a better indicator of service the percentage of claims processed before payment was due?

Answer: In processing a claim, the relationship between the date of filing and date of entitlement has a great deal to do with when payment is received. For example, a claim for retirement benefits usually is filed as many as 3 months in advance of entitlement. We are now reviewing our District Office Workload Report with a view toward obtaining standardized, consistent and accurate work measurement.

Question: Why don't you also measure the percentage of postentitlement actions processed before the next check is due?

Answer: Most postentitlement actions are processed within one benefit check payment cycle. SSA must coordinate its beneficiary records with the Department of the Treasury, which actually issues the payments. Both agencies must adhere to strict processing schedules in order to ensure that benefits are issued timely each month. The timing of the report of the postentitlement event (e.g., change of address) relative to SSA's and the Department of the Treasury's processing schedules is the single most important variable in telling how soon the event will be reflected in the benefit check. It is always SSA's goal to improve the timeliness of our processing. Our Claims Modernization Project includes initiatives not only to improve the processing of both claims and postentitlement events, but also to measure additional indicators of service.

Question: What have you done during the past year to ensure the integrity of your workload data that indicate the amount of work processed and pending?

Answer: Annually, in preparation of the SSA budget, the SSA workload structure and the methods used for counting the work processed and pending are reviewed. Wherever possible, workload counts that are by-products of systems processing are used. These are generally more accurate than counts that are obtained by manual tally methods. A large portion of the workload reports for district offices are automated by-products of systems processing. The past year studies of district office workload reporting were initiated with the objective of further automation and ensuring that we obtain consistent and accurate workload measures in a cost-efficient manner. These studies are showing promising results, and further automation of district office reporting next year is underway. In addition to the annual workload reviews and continuing steps to further automate workload reporting, validation surveys are conducted. For example, the past year several onsite surveys of procedures being used by the district offices to complete the District Office Workload Report were conducted. An onsite survey of workload reporting procedures used in the Annual Wage Reporting process at the SSA Wilkes-Barre Data Operations Center was also conducted.

Question: For fiscal year 1988, the Social Security Administration estimated savings of 2,134 workyears from field office systems enhancements. Numerous problems caused by systems overload have occurred, and software is not being released as scheduled. How do the systems performance levels assumed in preparing the fiscal year 1988 budget estimates compare with actual experience so far this fiscal year?

Answer: Early in FY 1988 there were systems performance problems. A bottleneck was caused by the security system that SSA uses to verify that only authorized personnel process claims. Also, as we phased-in use of the new terminals, we experienced performance difficulties with the old SSA Data Acquisition and Response System (SSADARS) because there were more SSADARS transactions than originally anticipated. These problems have been largely overcome. We are aggressively pursuing the claims modernization system and expect substantial savings from it in FY 1988 and FY 1989. We have revised our estimate of savings for FY 1988, since the FY 1988 President's budget was prepared, to take into account delays which have occurred in implementing software for the modernized claims system.

Question: Will the performance problems and delays result in less savings from the field office systems enhancements than originally estimated for fiscal year 1988?

Answer: In the FY 1988 budget, SSA had estimated a savings of 2,134 workyears from field office systems enhancements. The FY 1988 column of the FY 1989 President's budget projects savings of 1,228 workyears in FY 1988. These estimates reflect fewer workyear savings primarily due to delays in implementing the software programs which process claims to final payment and issue notices. Although there were systems performance problems in early FY 1988, these problems have been overcome and we believe that we can achieve the savings that we currently have budgeted. Revising the estimates for new information and current experience in this and other areas is consistent with our regular budget review process and with the promise that was made to the Congress when the overall plan for reducing full-time equivalents was announced.

Question: One of the objectives behind increasing telephone services is to improve the services provided to beneficiaries in the postentitlement area, which includes such basic transactions as change of address, change of employment status, and many others. However, GAO and others have noted that SSA has not completed the redesign of its postentitlement software. How can SSA expect to improve telephonic "postentitlement" services for the public when it has not completed this critical project?

Answer: SSA's existing postentitlement (PE) software effectively processes our PE actions. The redesign of our PE software represents an enhancement. We expect telephonic postentitlement improvements because we are better educating the public that SSA business can be completed by phone. We are also improving our telephone accessibility by the use of a single 800 number for the entire U.S. population. Finally, we are making SSA telephone service available for longer periods of time (service will be available from 7 a.m. to 7 p.m. for all types of calls, and some kinds of business can be conducted on a 24-hour basis).

Question: In the private sector, costs associated with toll free service are normally offset by savings elsewhere. What savings will accrue for the Social Security Administration, should toll free service be implemented?

Answer: This budget request includes $16.9 million in FY 1988 and $28 million in FY 1989 for the purchase and installation of equipment and line charges related to the national "800" number service initiative. There are no workyear savings budgeted. The nationwide 800 number is not designed as a cost-saving measure, but a means of improving the quality of the telephone service we currently provide to the public.

Question: How much do you plan to spend on software development in fiscal 1989?

Answer: Our budget request includes $18.2 million in FY 1989 for ITS software development and systems analysis. This represents 32 percent of total FY 1989 ITS costs not designated for ongoing operations, maintenance and telephone line charges.

Question: How much more do you need to finance the postal rate increase which went into effect during April 1988?

Answer: The postal rate increase that went into effect on April 3, 1988, will add about $16 million to SSA's postage costs in FY 1989. We are looking for ways to absorb this increase within the total appropriation requested.

Question: Last December, your Deputy Commissioner for Management indicated that you planned to send a questionnaire to 12,000 nonsupervisory employees. When do you plan to release the results of that survey?

Answer: The proposed survey of nonsupervisory employees has been postponed. We are currently conducting a series of management conferences throughout the organization to address the results of the first survey. The conferences will be concluded by the end of June 1988. After their conclusion, we are considering a followup survey of supervisors and managers before conducting a survey of employees.

Question: You state that 1,760 workyears, or almost half of your planned reduction in FY 1989, will be accomplished by automating retirement claims-taking in the remainder of your field offices (p. 89). How did you calculate the estimate and do you believe it's reliable?

Answer: The workyear savings shown in the FY 1989 appropriation request for field office systems enhancement are a cumulation of many factors. The estimates assume that terminals will be installed in all field offices and program service centers by November 1988; terminal installations are on schedule. The savings estimates are derived by examining processes as they now exist and predicting the amount of time that can be saved by making specific improvements to the claims process. These savings are offset by the time necessary to provide training on any process changes and for office disruptions caused during the installation of the terminals. Yes, I believe the estimate is reliable.

Question: Your budget justification (on p. 99) showed that the number of employees working full-time on union activities increased in 1 year from 62 to 80 and that expenses are expected to increase from $4 million in 1986 to $6 million in 1988. How many FTEs will be doing full-time union work in fiscal 1989 and at what cost?

Answer: As you are aware, SSA's labor contracts obligate the Agency to pay the costs of certain union expenses, such as salaries for official time to conduct union business. The budget justification reports that as of October 1987, 80 SSA employees were spending all or virtually all of their workday on union activities. Based on a survey taken in April 1988, that number has increased to 90. It is unknown at this time what union-related work will cost the Social Security trust funds in FY 1989. Given recent history, there is no indication that the costs will decrease. It should be noted that the $6 million in FY 1988 union costs represents the Social Security taxes paid by 5,900 average wage earners.

Question: What is the estimated fiscal 1989 cost for issuing Social Security cards generated by the Immigration Reform and Control Act, and what is the rationale for having trust funds meet the cost?

Answer: By FY 1989 we will have finished enumerating aliens who applied for legalization under the Immigration Reform and Control Act (IRCA), with the exception of a small number who may still qualify as special agricultural workers through November 30, 1988. The remaining SSN workload related to IRCA involves issuance of replacement cards for individuals (citizens or aliens) using the SSN card as evidence of work authorization under the employer sanctions provisions. We have included $2.4 million in FY 1989 to cover this work.

Because of SSA's responsibility for maintaining accurate records of workers' earnings for Social Security program purposes, it is in SSA's interest to assure that all workers have--and use--SSN cards that correctly reflect their names and numbers. It is also appropriate that trust fund monies pay for issuance of new and replacement SSN cards, regardless of the reason they are requested. I should also point out that the Immigration and Naturalization Service, U.S. foreign service posts and others assisted in the enumeration of the newly legalized aliens which, in fact, saved money for the trust funds.

Question: In June 1987, you announced that SSA was redirecting its systems modernization efforts. This "redirection" was to be reflected in revised budget submissions to the Congress, and in a revised plan. Has this plan been completed, and if so what are its major aspects?

Answer: SSA has reassessed and refocused its systems strategy, consistent with recommendations from GAO and the Congress. The overall strategies have been established and the FY 1988/FY 1989 budget plan for systems reflects this refocusing of SSA's systems modernization efforts. The new strategy:

- uses the ASP as a guide to provide better overall direction to systems planning;
- renews emphasis on customer service as the guiding principle in all systems activities;

- places more emphasis on software development, now that SSA has a delivery system of efficient hardware and telecommunications equipment; and
- improves project management so that efforts and resources match needs.

Question: How will the revised plan impact on SSA's budget?

Answer: Some major areas of expenditure planned for FY 1988 and FY 1989 reflect SSA's refocusing of systems modernization efforts. Briefly:

- SSA plans to increase the use of contractor support in the development of modernized software applications and in the design of an efficient data management system. Implementation of Software Engineering Standards will be completed and, in FY 1989, SSA plans to issue task order contracts to obtain contractor support for systems development, programming, testing and systems management projects on an as-needed basis. SSA will continue the services of an integration and management contractor to assist in planning and managing modernization activities and to perform specific tasks related to software engineering and integration and implementation of the Data Base Architecture project.

- This budget request reflects expanded use of telephone service as an alternative to walk-in office visits, in order to improve service to the public. The budget provides for acquisition of replacement equipment in field offices, teleservice centers, program service centers and data operations centers; additional telephone lines to ensure quicker service; and implementation of a plan to provide nationwide "800" telephone number service by October 1, 1988. This plan will consolidate telephone answering workloads and afford the public an enhanced, convenient option for transacting Social Security business. In FY 1988, needed hardware will be purchased, including modern, state-of-the-art automatic call distribution equipment.

- Finally, the budget provides for additional acquisitions of microcomputer systems and supporting software for components at SSA's headquarters and regional and field offices to equip them with modern office automation capabilities. This is a consolidation of existing projects to produce a compatible, interconnected personal computer base at SSA in a well-managed manner.

Question: Can the necessary planning, analysis and coordination for the revisions take place in time to ensure that fiscal year 1989 funds are used wisely?

Answer: Some of the major areas of expenditure budgeted for FY 1988 and FY 1989 reflect SSA's refocusing of systems modernization efforts. The key items are: (1) development of modernized software applications; (2) expanded use of telephone service; and (3) the acquisition of microcomputer systems for headquarters and field office components as we move toward modern office automation capabilities. Tracking mechanisms are already in place to assure the funds devoted to these efforts are used wisely.

Question: In December 1987 you directed SSA's senior management to reexamine the FY 1988 ITS budget. A revised plan was approved in February 1988, and it included many changes for ADP projects planned for both fiscal years 1988 and 1989. Please explain for the Committee your reasoning for all of these changes.

Answer: A critical factor in successfully completing SSA's systems modernization is better management of the ITS budget. We took a hard look at the ITS budget to assess project costs and schedules, to refocus available resources on the highest priorities, and to ensure that there will be no ITS budget carry-over into FY 1989. We revised project funding allocations as necessary to match current cost estimates, cancelled initiatives that were no longer necessary, and deferred to a later fiscal year those projects that were behind schedule and could be delayed. We reprogrammed available resources to move forward with projects required to implement the ASP and meet other critical Agency needs.

Improving SSA's data processing software has always been a key objective of our systems efforts. The restructuring of the ITS budget reflects decisions reached on how best to perform some key software development efforts. Some modernized software development originally planned for completion contracts will now be performed using both inhouse staff and contractor resources available through task order contracts. This strategy will allow SSA to better manage software modernization efforts, to ensure that contractor performance meets SSA's expectations, and to obtain economics in software development.

Question: Are these changes related to the redirected systems modernization plan?

Answer: Many of these changes are related to the redirected systems modernization plan. For example, a key objective of the refocusing of SSA's systems modernization is renewed emphasis on customer services. We are working on the development of a nationwide 800 number, so that anyone, anywhere in the country, will be able to get in touch with SSA 24 hours per day, 7 days per week by calling a single nationwide number. We shifted resources within our ITS budget to support this initiative. Another example is an additional project to expand direct deposit to allow beneficiaries to receive monthly benefits using electronic direct deposit.

Question: What impact did the overall reduction in the LAE account have on the fiscal years 1988 and 1989 ITS budgets?

Answer: Current spending plans for SSA's ITS budget include $220 million in both FY 1988 and FY 1989. All of the FY 1988 costs will be funded from carryover from prior years. FY 1989 resources will come from new budget authority as shown in our FY 1989 appropriation request. The funding levels for FY 1988 and FY 1989 are consistent with the refocused systems plans.

Question: Commissioner Hardy, you stated in a June 16, 1987 letter to Senator Lawton Chiles that SSA needs to refocus their systems modernization. You explained that "with regards to improving existing software, refocusing means completing full implementation of the Software Engineering Standards by the end of this year and enforcing the standards carefully and strictly." Have these standards been fully implemented, and are they being "carefully and strictly" enforced?

Answer: Yes. The Software Engineering Technology (SET) standards have been implemented for all new projects, including those that impact existing software. Approximately 1,255 managers, project leaders and project team members have been trained to use these standards.

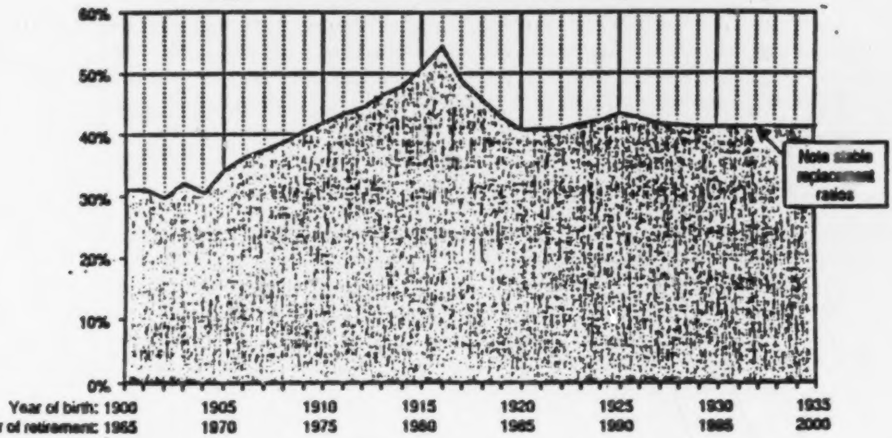
We have three mechanisms now in place to enforce the standards:

- o Quality control checklists are used for each life-cycle stage;
- o Configuration Control Boards at various management levels have been established to review key life-cycle documents for adherence to SET standards; and
- o We are conducting quality assurance audits of completed life-cycle products.

Question: There has been a lot of attention to the issue of "notch" babies--seniors born between the years 1917 and 1921, and perhaps those born between 1922 and 1928 as well. Is it accurate that beneficiaries born between these years will receive smaller benefits than those born earlier in the century?

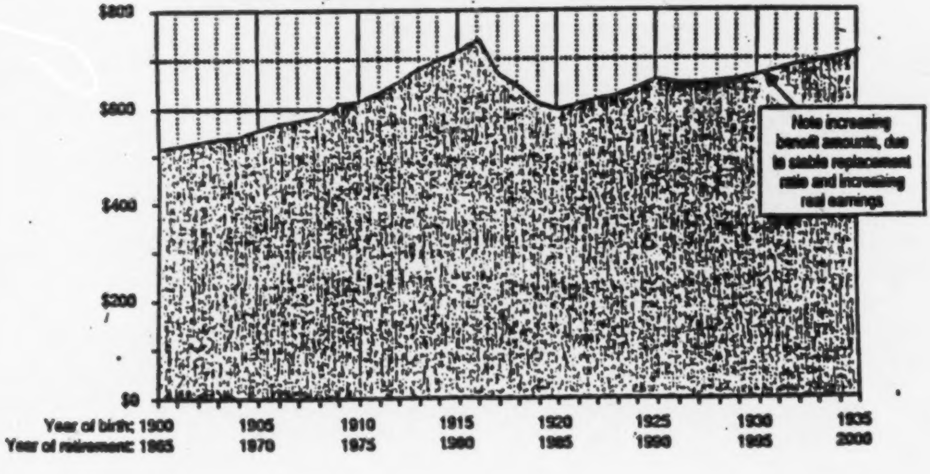
Answer: Replacement rates (benefits as a percent of pre-retirement earnings) for people born after 1917 are as high, or higher, than replacement rates for any other group born earlier or later, except for workers born in the period 1910-1916--the group which received windfalls due to the flaw in the 1972 legislation. Replacement rates for people born in 1900-1935 are shown in the chart which follows:

## Social Security Replacement Rates for Age-65 Retirees with Average Earnings



Benefits for people born in the 1917-1921 period--frequently characterized as the notch years--are not lower than benefits for all of those born earlier in this century. Retirees who were born before 1910 and who took Social Security benefits at normal retirement age were not affected by the unintended windfall caused by the flaw in the 1972 legislation and received lower benefits than those born after 1916. People retiring in the future will receive benefits higher than the 1917-1921 group because their wages on which their benefits are based are assumed to be higher. This is an expected result and does not indicate that people born in 1917-1921 are treated inequitably. The following chart shows benefits (in terms of 1988 dollars) for people born in 1900-1935.

## Social Security Benefits (in 1988 Dollars) for Age-65 Retirees with Average Earnings



Question: How did the "notch" come into existence, and what do you recommend be done about it?

Answer: In 1972, in order to maintain the purchasing power of Social Security benefits after a worker retires, Congress provided for automatic cost-of-living adjustments beginning in 1975. However, the computation method in the 1972 legislation was flawed. It overadjusted the benefits of workers retiring in the future for increases in the cost of living and resulted in unanticipated increases in benefit rates.

In 1977, Congress enacted a major, well-thought-out revision of the Social Security benefit structure that was designed to restore more appropriate benefit rates and help solve the financing problems facing Social Security at that time. The new and more equitable 1977 computation method applies to all workers born in 1917 and later.

The "notch" occurs because workers born between 1910 and 1916 receive unintended windfall benefits. They receive these windfall benefits because of the flawed 1972 benefit computation method which overcompensated for inflation.

No inequity has occurred with regard to those people born in 1917 and later. They are receiving appropriate benefit levels that were intended by Congress and that compare favorably to benefit levels for people born prior to 1910 who did not profit from the unintended windfall caused by the flawed 1972 computation method.

Question: What would it cost if S. 1830 were enacted (Senator Sanford's bill) to correct the "notch inequity"?

Answer: That bill (S. 1830) would cost about $67.5 billion over 1988-1996. Even though the Social Security trust funds are now building up a reserve, the trust funds could not afford to pay billions of dollars in additional benefits. The reserves accumulating in the trust funds now and in the future are needed to pay benefits to workers retiring in the future. There is no "extra" money in the trust funds.

Question: By the end of fiscal 1989, another $45 million will be added to the surplus of Social Security trust funds, for a total balance of $147 billion. By 1993, these trust fund balances are projected to grow by another $300 billion, for a grand total of $448 billion. Do you see any adverse effects resulting from this dramatic growth in trust fund balances?

Answer: Right now, trust fund reserves on hand are enough to pay about 5 months of benefits. By the end of FY 1993, the reserves are estimated to be sufficient to pay about 15 months of benefits. I believe that increasing the reserve over current levels will have a very positive effect in helping to rebuild public confidence in the financial condition of Social Security.

Question: Right now, the growing trust fund surplus masks the true size of the Federal budget deficit, but when it becomes necessary to disburse these funds when the "baby boom" generation starts retiring a couple of decades from now, the Federal deficit may suddenly look huge. What thoughts do you have about the potential threat to retirement benefits, once Social Security outlays begin to far outstrip receipts?

Answer: The budgetary effect of redeeming trust fund investments to help pay benefits when the baby boom generation retires will depend on many things at that time, including the balance of the Federal budgetary income and outgo other than Social Security, how wealthy the Nation is then, and how close to actual experience our current economic and demographic assumptions prove to be over the intervening years. I believe we need to encourage national debate on the future of Social Security, including the issue of the current buildup and eventual drawdown of the trust funds. I welcome the opportunity to participate in these discussions.

Question: While the Social Security Administration uses various measures of its operations to assess managers' and employees' performance, goals for processing of both measured and nonmeasured workloads have not been defined. Why hasn't the Social Security Administration defined "service quality" and established accountability mechanisms to ensure quality service is provided?

Answer: We have defined service quality. It is paying all legally entitled individuals accurately and timely and providing courteous and dignified service.

Question: How can performance be meaningfully evaluated without an idea of how performance should be?

Answer: We measure performance both by comparing service among our offices and regions and by continuously working to improve the service we provide.

Question: When the Social Security Administration announced in fiscal year 1985 its intention to reduce staffing by 17,000 positions, it assumed that systems modernization would occur on schedule and that there would be no new workloads. The slippage in systems modernization is well known, and the tax reform and immigration reform acts of 1986 created substantial new workloads. Moreover, certain of the initiatives the Social Security Administration assumed would result in reduced staff needs, such as a "streamlining" of field office service delivery, have been scaled down or eliminated from the plan entirely. How is it that many of the conditions assumed for the staff reductions have not been met, yet at least through fiscal year 1988, the staff reduction targets have been met?

Answer: The original FTE reduction plan outlines the broad elements of a plan to reduce SSA's FTEs by about 17,000 between FY 1984 and FY 1990. Although many of the factors contributing to FTE reductions have changed, SSA has exceeded its FTE targets through FY 1987 and expects to meet them in FY 1988 and FY 1989 while continuing to provide good service to the public. When the original plan was formulated, SSA anticipated that the individual elements would change and that each year, as the budget was developed, we would reevaluate SSA's FTE needs. Although savings from claims modernization (which was assumed to account for 31 percent of the reductions in the original plan) have occurred later than planned and other elements of the original plan have changed, we have achieved substantial workyear savings from initiatives which were not specified in the original plan. Examples of such initiatives which have produced significant workyear savings are:

- More effective targeting and other improvements in the SSI redeterminations process;
- Increases in the amounts of annual wage reports received on magnetic media;
- Software improvements to several operating systems which reduce the number of unproductive alerts, exceptions and reviews in the field offices and processing centers; and
- Automation improvements, other than claims modernization, such as refinements to the claims automated processing system, automating SSI overpayment notices and automating the third party query system for furnishing benefit payment information to State welfare agencies.

Question: Considering the significant slippage in systems modernization and the fact that most of the reductions originally planned for fiscal years 1989 and 1990 were predicated on systems modernization, how can further staff reductions be justified?

Answer: Although savings from claims modernization are occurring later than projected in the original FTE plan, substantial savings are expected from claims modernization in FY 1988 and FY 1989--a total of 2,988 workyears over the 2-year period, with additional savings expected in FY 1990. Additional savings will result from other management, systems and procedural improvements, such as:

- More effective targeting of SSI redeterminations to be processed;

- Systems generation of clear SSI overpayment notices;
- Change of address processing modifications and automation improvements which will reduce manual workloads in field offices;
- Software improvements to several operating systems which reduce the number of unproductive alerts, exceptions and reviews in the processing centers;
- Reductions in staff/support functions; and
- Improvements in the ratio between operations support workyears and direct processing workyears.

Also, it is important to note that the original FTE reduction plan assumed that less than one-third of the overall reduction of 17,000 FTEs would be based on savings from claims modernization.

Question: The Social Security Administration measures field office performance and predicates managers' merit pay awards mainly in terms of how well and timely initial claims workloads are processed. Many aspects of service to the public--for example, accessibility by telephone, and timeliness of direct deposit requests and administrative law judge effectuations--are not systematically measured. Many critics of SSA's staff reductions contend that erosion in service will first and most strongly occur in the nonmeasured aspects of operations. Does the official emphasis on initial claims workloads represent a balanced approach to overall workloads?

Answer: SSA does have a balanced approach to overall workloads. Initial claims are very important, but we do not overemphasize them to the detriment of other workloads. Over the past several years, we have seen an increased emphasis on providing a balanced approach to all workloads and to the quality of the service we deliver.

Field offices report weekly on the status of 56 different workloads. This report includes receipts, clearances, and the pending balance for 26 of the 56 different workloads. Of these 56 workloads, only 9 are initial claims. Included among the remaining 47 are postentitlement type workloads such as change of address actions, Social Security number work, and appeals data such as SSI appeal effectuations pending and the number of those appeal effectuations pending over 60 days.

As part of a balanced approach to service delivery, the field offices not only report on what they do, but also on how they perform the various workloads, for example, how many actions were processed over the telephone, or how many appointments were held.

Question: What mechanisms provide SSA with reasonable assurance that nonmeasured workloads are processed in a timely manner?

Answer: Although we do not measure every single workload, some of which account for less than one-half of a percent of our national effort, we believe that we are measuring the full range of our workloads and that the manner in which we do so (receipts, clearances and pendings) provides us with a vehicle for identifying potential problem areas as they develop so that corrective action can be initiated. We are closely examining the District Office Workload Report to ensure that we have appropriate and accurate workload reporting.

Question: Since managers are assessed on whether they satisfy certain performance measures, many people have contended that these indicators would be the last to reveal service deterioration, and are, in effect, lagging indicators. Specifically, what indicators do the Social Security Administration have that would serve as early warning indicators of service problems?

Answer: In addition to the 56 workload indicators discussed previously (26 of which are tracked by receipts, clearances and pendings) field offices are visited regularly by management officials of all levels, including headquarters officials. These visits provide first-hand knowledge of the state of the service delivery process that cannot be gained by a review of statistical data in a remote location.

We are also pursuing the establishment of a regular survey of the public, concentrating on persons who have recently visited a Social Security office, in order to develop an understanding of the public's view of the quality of our delivery of service and any problems they may have encountered. Such a study was conducted in June 1987 by the Inspector General's office. At that time, 85 percent of the public surveyed rated our service as good or better. A new survey by the Inspector General, the results of which are not yet complete, shows similar positive results.

We also apprise the Congress on a quarterly basis of some 25 service indicators including workload indicators.

Question: GAO reports have shown that Social Security field office productivity varies widely among offices and regions. In both fiscal years 1987 and 1988, the Social Security Administration has attempted to reduce the productivity variance among regions by reducing staffing in the more productive regions by less than the proportionate reduction in the lower productivity regions. What is the historical reason for the variance in productivity among the Social Security Administration regions?

Answer: Variance in productivity rates may result from many factors, including demographic characteristics of the population served, and the competitiveness of the local labor market. We have found also that careful attention to how we manage and allocate FTEs to the regions plays an extremely important role in productivity. For example, between FY 1985 and FY 1987 as SSA focused its efforts on FTE management, regional productivity increased approximately 20 percent and the gap between the most productive and least productive region closed by about 20 percent.

Question: The Social Security Administration has not instructed the regions to follow suit and reduce the productivity variance among field offices. Why hasn't it done so and what efforts are being made to improve productivity by the various regions?

Answer: The Agency has instructed the regions to improve local productivity and many activities are underway in the regions as a result. SSA is providing local management with the tools to analyze and take action on their own productivity concerns.

By implementing GAO's recommendation that SSA develop a system to identify targets of opportunity for increased efficiency, we are looking closely at local productivity. The recently established productivity measurement methodology will provide managers with regular reports on their office's productivity in five categories of work. This will provide a starting point for additional analyses. We are working to automate these reports.

Each of the regions has appointed a productivity council that focuses on regional productivity improvement efforts. All regions have formalized a process in which efficient operating practices are shared with other offices in the region and with other regions.

Question: If much of the staff reductions are being accomplished primarily through increased productivity, does this not indicate that the Social Security Administration has not had accurate indicators of what its true staff needs are?

Answer: No, one should not conclude that SSA does not have an accurate assessment of its staffing needs. Productivity increases have primarily resulted from the automation of labor-intensive, paperwork-oriented activities, as well as numerous management initiatives to streamline work processes, such as the elimination of millions of unproductive workload alerts and exceptions and the more precise targeting of Supplemental Security Income eligibility redetermination actions. Such enhancements and improvements have enabled the Agency to reduce staff in recent years and thus show significant productivity increases. Also, we have recently established a productivity measurement methodology which will provide regular reports for use in analyzing management and staffing at the office level.

Question: Doesn't this suggest a need for national workload standards, so that the Social Security Administration can accurately establish what its staff needs are, and where future productivity improvements can and should be made?

Answer: The Social Security Administration has an extensive budget process that includes the use of a variety of management information sources to determine current and future staff needs. We are studying the issue of new standards, including a pilot study in two offices using industrial engineering techniques. However, the Agency is currently in a period of rapid change as automation and the resultant downsizing alter almost all of our work processes. Under such conditions, any standards established at this time would, in all likelihood, become outdated very quickly. Therefore, while SSA is looking at this issue, the final resolution as to the feasibility of implementing such standards will not occur for some time.

## QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

Question: The fiscal year 1989 budget request calls for a reduction of 4,300 FTEs, the continuation of Social Security's Systems Modernization Plan, and the implementation of a nationwide "800" number. Will there be any Social Security offices closed as a result of these staffing reductions?

Answer: The FY 1989 budget request reflects many initiatives which work in concert to meet the Agency goal of providing quality service to the public in general and to the beneficiaries of SSA programs in particular. It also reflects our commitment to provide these services to an ever changing society in the most efficient manner possible. While over time this will require changing the structure of some jobs, creating new positions, retraining some employees, and refining our field office structure, let me again emphasize that these initiatives do not entail the loss of jobs or benefits, nor force the closing of Social Security offices.

In the last year, we consolidated about 9 of the 1,300 offices SSA has nationwide. Additionally, we converted 8 others to a different type office, for example, a district office to a branch office. We have no plans to do anything dramatically different in future years with respect to our field office structure than we have done during the past year.

Question: Please provide for the record a list of all Social Security offices in West Virginia and the staffing level for each.

Answer: Below you will find a list of Social Security offices in West Virginia and the staffing levels of each as requested. It is based on data available as of March 25, 1988.

| Offices | Total Staff |
|---|---|
| Charleston, WV | 39 |
| Wheeling, WV | 29 |
| Parkersburg, WV | 28 |
| Huntington, WV | 34 |
| Clarksburg, WV | 35 |
| Elkins, WV | 13 |
| Bluefield, WV | 32 |
| Morgantown, WV | 13 |
| Beckley, WV | 26 |
| Logan, WV | 18 |
| Welch, WV | 22 |
| Martinsburg, WV | 15 |
| Fairmont, WV | 14 |
| Montgomery, WV | 11 |
| St. Albans, WV | 14 |
| Williamson, WV | 10 |

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## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

Question: The budget justification for FY 1989 indicates that you project a 4 percent increase over FY 1988 in Supplemental Security Income (SSI) recipients who are blind and disabled. In fact, the justification shows a 20 percent rise in blind and disabled SSI recipients since 1984. What is the reason for this continued growth in blind and disabled SSI recipients?

Answer: First, over the last few years, the number of applications for blind and disabled SSI benefits has been increasing slightly, and more have mental impairments. In 1985 there were 22,490 SSI disabled recipients with mental impairments. By 1988 the number had more than doubled to 51,850. Second, the SSI blind and disabled population is younger than those who receive Social Security disability benefits and, as a consequence, has a longer tenure on the SSI rolls. In 1980, the number of SSI blind and disabled children totaled 228,600 and represented 5.5 percent of the SSI caseload. By the end of 1987, the number of children had increased to 288,700 or 6.5 percent of the total SSI caseload. Third, once someone is entitled to SSI payments based on blindness or disability, he remains in the "blind and disabled" category as long as he is eligible, regardless of age. This is not the case in the Social Security program, where a disabled person is counted in the retirement category once he attains age 65. In 1980, the number of SSI blind and disabled over age 65 totaled 413,000 and represented 9.8 percent of the SSI caseload. By the end of 1987 the number had increased to 556,000 or 12 percent of the caseload.

Question: Are we not making progress in this country in the prevention and treatment of disabilities?

Answer: While SSA is not directly involved in the prevention and treatment of disabilities, we do think progress is being made. SSA is increasing its efforts to develop effective vocational rehabilitation services. However, despite advances in this area, the number of blind and disabled SSI recipients continues to grow because of the reasons stated earlier.

Question: Do you expect the growth of 4 percent per year in the disabled SSI population to continue?

Answer: Yes, based on recent actual experience, we have budgeted for a growth rate in the blind and disabled rolls of 4.5 percent in FY 1989.

Question: It has come to my attention that Social Security benefits for the nonblind disabled are significantly less than for their blind counterparts. In particular, the incentives and supports to return to work are substantially less for the nonblind.

I'd like you to elaborate on these discrepancies involving title II and title XVI. Why, for instance, should a mentally retarded person or the victim of a traumatic head injury lose Social Security disability insurance benefits if his net income exceeds $300 per month, while a blind person retains the same benefits with a net income up to $680 per month?

Answer: Over the years, the Congress has enacted legislation to provide special rules under the DI and SSI programs for persons disabled by blindness. For example, the DI program contains different work requirements for workers who are blind than for those with other disabilities; there are different cash benefit provisions for workers and childhood disability beneficiaries who are blind, age 55 and older, and who are engaging in noncomparable substantial gainful activity (SGA); and there are different SGA earnings guidelines for the blind than those for nonblind disabled individuals. The SSI program has an SGA eligibility test for nonblind disability claimants, but not for blind claimants; and the earned income exclusions for work-related expenses are different for those applicants and beneficiaries who are blind than those who are not blind.

Up until 1978, the earnings considered sufficient to show an ability to engage in SGA were the same under the DI program for the nonblind and the blind disabled. However, the Congress enacted legislation which provided, beginning in 1978, for a higher SGA earnings level for blind disabled individuals than the level for the nonblind disabled. The SGA level for the blind was tied into the earnings test exempt amount which applies to retirement and survivor beneficiaries aged 65-69. The current SGA dollar amount of $700 per month for blind beneficiaries has been set pursuant to the Social Security law (in 1987, the SGA level for the blind was $680 per month).

The law requires the Secretary of Health and Human Services to prescribe, through regulations, the SGA criteria for nonblind disabled individuals. Under current regulations, a disabled beneficiary who is not blind will ordinarily be considered to be engaging in SGA if his earnings average more than $300 per month. When the Congress established the higher SGA amount for the blind, the House/Senate conference report accompanying the legislation stated that a different SGA amount was being established for blind persons and the conferees did not intend that it be applied to the nonblind.

The Disability Advisory Council, which was mandated by the Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272) and issued its report in March 1988, noted its concern about the preferential treatment of people who are blind as compared to those with other disabilities, not only with respect to the SGA issue, but in all other areas as well. The Council recommended that the SGA levels should be made equal for both the nonblind disabled and the blind, but stated that having all disability beneficiaries subject to the present SGA level for the blind is not the appropriate way to equalize the levels. The Council recommended, instead, that the level of earnings which constitutes SGA for blind individuals now receiving benefits should be held constant at the current level. However, blind individuals who newly apply for disability benefits should be subject to the same SGA level that is applicable to all other individuals with disabilities. We are carefully reviewing all of the Council's recommendations.

## QUESTIONS SUBMITTED BY SENATOR BARBARA A. MIKULSKI

Question: Did you buy ergonomic furniture with the $64.7 million as directed by the Senate Conference Report?

Answer: In its FY 1988 budget justification to the Congress, SSA explained its plan for use of the $64.7 million as follows:

> "Because of GAO and congressional concerns and in recognition of fiscal constraints government-wide, SSA is reexamining its furniture procurement plans. SSA's FY 1988 budget proposes to make the $64.7 million earmarked for ergonomic furniture available for regular administrative expenses as needed in FY 1988. We estimate that SSA will obligate $30 million of it for ergonomic furniture, and the remaining $34.7 million for regular administrative expenses."

The Committee report on the FY 1988 appropriations request indicated the desirability of adequate furniture, and stated that the Commissioner was to use her professional judgment in determining how much would be appropriate to spend.

We believe that $30 million is a reasonable amount to spend on ergonomic furniture in 1988, and we have obligated that amount. We have requested an additional $30 million for FY 1989.

Question: Recognizing that the most important factor in ergonomic furniture design is adjustability, what are the adjustable features on the desk you are providing for the employees?

Answer: In addition to providing the standard desk and keying heights, adjustable keyboard drawers are being installed under the work surface for individual keying height preference. With ergonomic furniture, the adjustability you refer to is achieved primarily through the adjustability of ergonomic chairs.

Question: If there are no adjustability features - recognizing that people are of different sizes and shapes and some have physical limitations, you are purchasing modular furniture with funds appropriated for ergonomic furniture, is that correct?

Answer: The modular furniture being purchased has ergonomic features to accommodate the majority of employees. Employees with physical limitations are accommodated on a case-by-case basis. It should be noted that ergonomic furniture is the generic name. Both "modular" and "systems" furniture are ergonomic.

Question: As of March 1988, is it true that 800 offices have terminals installed?

Answer: As of March 1988, a total of 637 field offices had terminals installed.

Question: How many of the 800 offices have new desks?

Answer: As of May 16, 12 field offices have ergonomic furniture, with approximately 230 more offices scheduled for installation by the end of this year.

Question: Were there desks purchased in 1986 and 1987?

Answer: SSA purchased this kind of furniture for pilot offices in fiscal years 1985, 1986 and 1987. The Committee report on the FY 1987 supplemental appropriation indicated that it had no objection to SSA spending up to $1 million on ergonomic furniture in FY 1987, even though $64.7 million was earmarked for ergonomic furniture beginning on September 30, 1987, and remaining available through FY 1988.

Question: Is the desk top adjustable to meet the needs of employees?

Answer: No, the desk top is not adjustable. Adjustability is achieved primarily through the adjustability of ergonomic chairs.

Question: Were these offices considered as furniture pilot offices? If so, why was modular furniture installed in some offices rather than ergonomic desks?

Answer: Yes, these 12 offices did receive new furniture as part of our furniture pilot project. We did install both modular furniture (in which the desks and other work surfaces are freestanding) and systems furniture (in which the desk and all other work surfaces are hung from brackets on the acoustical panels that surround the work station) in the pilot offices. Both types of furniture are considered "ergonomic" because they provide work surfaces at what is considered the proper height for using a computer keyboard over an extended period of time.

Question: Ergonomic environment calls for properly designed desks, chairs, lighting, heating, ventilation and air conditioning. So far you have provided ergonomic chairs that accommodate about 80 percent of the workforce. What steps have you taken to modify lighting? Other than providing proper temperature control for one terminal and printer designed for management use, what steps have you taken to upgrade HVAC to address employee needs?

Answer: We are doing the following to address lighting:

- We are providing shielded task lighting for each desk with an overhead storage unit to eliminate any shadows cast by the overhead unit and to provide the proper amount of light needed for handling papers and manuals at the desk.
- Ceiling light fixtures in individual field offices are relocated as needed based on the new office layouts for the furniture. The design contractor prepares what is known as a reflected ceiling plan when appropriate so that lighting changes can be studied and made.

Concerning HVAC needs, we issued a guide at the beginning of the site preparation phase that includes information for our regional offices to use to estimate the long-term heat load in each field office based on the number of computer devices to be installed. Based on these calculations, we have requested that the General Services Administration (GSA) make HVAC upgrades where necessary through the normal work authorization process. As we have always done, we work closely with GSA to ensure that our buildings are operated within GSA's temperature guidelines.

The question makes reference to providing proper temperature control for one terminal and printer designed for management use. We believe this refers to HVAC changes made to offices' SSADARS rooms. The rooms are not for management use, and the changes were made to accommodate special temperature requirements for the telephone equipment and the computer terminal controls which are kept in SSADARS rooms.

## HEALTH CARE FINANCING ADMINISTRATION

## STATEMENT OF WILLIAM L. ROPER, M.D., ADMINISTRATOR

ACCOMPANIED BY:

LEE MOSEDALE, DIRECTOR, OFFICE OF FINANCIAL MANAGEMENT AND PROCUREMENT

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES

### PREPARED STATEMENT

Senator CHILES. Our next witness is Dr. Roper. Dr. Roper, we would like to discuss several issues with you concerning the administration of the Medicare and the Medicaid programs. We are concerned about the Office of Management and Budget releasing the remainder of the $42.7 million of Medicare contractor contingency fund. We understand they have imposed a new matching offset requirement. That doesn't make much sense to us at all. I am particularly confused as to why this offset is needed, since OMB released $14.7 million without an offset and they have released the contingency funds in past years without any offset and we will want to talk to you about that.

In addition we want to learn more about your plans for the new Administrative Law Judge Hearing and Appeals Program. If you will introduce your associates and then proceed with the oral summary of your opening remarks and your full statement will be placed in the record.

[The statement follows:]

## STATEMENT OF WILLIAM L. ROPER

Mr. Chairman and Members of the Subcommittee, I am honored to appear before you today to present the Fiscal Year 1989 budget request of the Health Care Financing Administration. As the primary vehicles for Federal financial participation in the American health care system, the Medicare and Medicaid programs have been caught up in powerful crosscurrents of change throughout the first seven years of the Reagan Administration. Hospitals, physicians and other health care professionals, suppliers of medical products, employers, insurance companies, beneficiaries, and other participants in the health care system have had to react and adapt to some fundamental differences between the practice of medicine today and the ways services were provided and paid for in past decades. Economic and technological forces have combined with political and fiscal realities to reshape the programs administered by the Health Care Financing Administration and no end to this trend is in sight.

It is no surprise that our programs, and especially Medicare, have been subjected to as close Congressional scrutiny as any others in the Department of Health and Human Services or any other Department. As recently as December of 1987, the Congress and the Administration jointly developed yet another Omnibus Budget Reconciliation Act that makes sweeping changes in the conditions under which medical services for Medicare and Medicaid beneficiaries will be provided and financed. We also stand on the brink of enactment of catastrophic health insurance legislation that will expand the scope of protection afforded to the elderly and the disabled from crushing medical expenses.

The budget we present here today represents our vision of where we go from here--how we can move in the direction of a more decentralized system, with increased consumer choice and incentives for enhanced quality without excessive utilization. We were also mindful of continued upward pressures on health care spending. While the OBRA 1987 legislation reduced expected Medicare outlays and increased Medicare receipts by a total of $2.6 billion in FY 1989 and a total of $7.4 billion over the five years FY 1988 through FY 1992, Medicare spending under current law will still rise by 9.2 percent in FY 1989. The savings proposals in this budget would trim the increase in Medicare outlays by an additional $1.3 billion in FY 1989 and bring in $1.6 billion in new revenues to the trust funds, lowering the net increase in spending to 7.8 percent.

**Although most of the proposals are not intended for cost containment, regulatory initiatives will help slow the growth of Federal spending for Medicaid as well.**

**Within this framework of high expectations, constant change, and fiscal constraint, we have constructed a detailed request for funding for each of the appropriated accounts administered by the Health Care Financing Administration. I would like to summarize each in turn.**

## Grants to States for Medicaid

Medicaid will serve an estimated 25 million low income persons in the coming fiscal year. We are requesting $32.7 billion to fund benefits and administration of this Federal/State program in FY 1989, a $2.1 billion or 6.7 percent increase above our current outlay estimate for FY 1988. This figure takes into account a net cost of $313 million associated with various provisions enacted as part of OBRA 1987, including expanded coverage for children and pregnant women in low income families, increased payments to disproportionate share hospitals, certain nursing home reforms, and coverage for services furnished to the homeless outside clinics.

Also reflected in our current law request is $413 million in FY 1989 savings expected to result from a series of new regulatory initiatives. Our initiatives will encourage more cost effective health care, improve program administration and clarify payment policies to close loopholes. Consistent with the December budget summit agreement, no new legislative initiatives are proposed for Medicaid. However, one new Medicare legislative proposal (to hold the Part B premium at 25 percent of program costs) would produce a modest increase in Medicaid costs beginning in FY 1990.

## Payments to the Health Care Trust Funds

The account designated "Payments to the Health Care Trust Funds" encompasses various sums appropriated to the Medicare trust funds, but consists almost entirely of the Federal general revenue subsidy of the Supplementary Medical Insurance (Part B) program. Federal general revenues finance 75% of program costs. Our FY 1989 current law request for this account is $32.1 billion, a $6.2 billion or 24.0 percent increase over the FY 1988 amount. Like the increase in the premium, the increase in the Federal contribution to Part B reflects rapid growth in Part B program costs. Our legislative proposal to extend the Part B premium permanently at 25% of aged program costs would slow the rate of increase in the payments account beginning in FY 1990.

Although certain OBRA 1987 provisions and legislative proposals set forth in this budget are aimed at slowing the rate of increase in spending for physicians' services, this remains one of the major challenges facing both the Administration and Congress. It is a complex problem that will not respond to simple solutions. We plan to pursue a variety of physician payment reform studies and options. For example, one promising area is to evaluate cost control efforts made by the private sector through preferred provider organizations.

## Program Management

Through its program management accounts, HCFA oversees the administration of both Medicare and Medicaid, monitors the quality of services provided to beneficiaries, conducts policy relevant research, and funds the claims processing and review activities of the fiscal intermediaries. The total FY 1989 request of $1.8 billion is made up of $0.1 billion appropriated from general funds and $1.7 billion authorized to be transferred from the Medicare trust funds. Amounts are requested for the following activities:

### Research

We are requesting $32 million to fund HCFA's research program in FY 1989, an 18.5 percent increase over the FY 1988 appropriated amount of $27 million. About two-thirds of the funds requested would come from the Medicare trust funds and one-third from general revenues. As in recent years, more than half would be needed to fund congressionally mandated projects.

The pace of change in the health care sector of our economy, both public and private, requires that we invest heavily in a research program aimed at keeping ahead of the curve. The Prospective Payment System, while imperfect and in need of further refinement, has radically improved the way we pay for hospital services under Medicare by introducing incentives for cost consciousness without sacrificing quality. If we are to make similar progress in rationalizing Part B reimbursement, meeting the costs of long term care, encouraging less costly alternatives to fee for service medicine, and so on, then a substantial and carefully focused research program is essential. Priorities for the coming fiscal year include:

- study of physician payment issues, including volume and intensity of services, pricing of procedures, and refinements to current payment methods;
- study of post-discharge care needs, including testing of a prospective payment system for home health services;
- study of the cost and effectiveness of a demonstration providing comprehensive services for Medicare beneficiaries who are victims of Alzheimer's disease.

Medicare Contractors

Through the Medicare Contractor budget, HCFA ensures that beneficiaries receive prompt, accurate and courteous service on their claims, providers and suppliers are treated fairly as business partners, and taxpayer dollars are conserved. The contractor budget provides funding for operating costs incurred by Blue Cross and Blue Shield plans and other private health insurance companies that assist HCFA in administering the Medicare program. We are requesting a total of $1.4 billion to fund these contracts in FY 1989, a significant 24 percent increase over the FY 1988 program level of $1.1 billion.

Increased funding is needed to:

- meet claims processing costs which have been driven upward by increases in claims volume, inflation, and the requirements of legislation (including, for example, the requirement that participating physician claims be paid no sooner than 14 days and no later than 18 days in FY 1989 and that all other claims be paid between the 15th and 25th day) despite consistent reductions in unit costs per claim processed;

- expand payment safeguard activities to implement new medical review screens to help hold down Part B costs and hence the premium, increase the number of medically trained carrier professionals, focus prepayment reviews on high dollar and frequently performed services, and conduct audits keyed to OBRA 1987 provisions (e.g., disproportionate share payments, graduate medical education costs);

- invest in productivity improvements including recruitment and retention of participating physicians, implementation of certain OBRA 1987 provisions, and continuation of efforts at standardizing claims processing systems.

Over the past several years, the Medicare contractors have been required to respond to a staggering array of legislative and regulatory changes. Only if adequate resources are provided can they continue to meet these challenges. In addition, we believe that we can save a total of $3.5 billion in benefit dollars in FY 1989 if audit and review activities are stepped up as we have proposed.

## State Certification

Through the State Survey and Certification program, HCFA ensures that facilities participating in Medicare and Medicaid meet certain quality and safety standards. Institutional and noninstitutional providers of health care services to beneficiaries are surveyed before they are permitted to participate in the programs and periodically thereafter to demonstrate continued compliance with program rules. We are requesting a total of $121 million for this activity in FY 1989. In addition to the $55 million current law amount required for Medicaid survey and certification which is included within the Grants to States for Medicaid total, we are requesting $66 million for Medicare State survey and certification.

This $66 million figure is the same as our FY 1988 appropriation, but includes a larger proportion devoted to direct survey activities with a corresponding reduction in spending for support contracts. With this sum, we will be able to survey 69 percent of all providers and suppliers participating in Medicare, including 100 percent of all skilled nursing facilities and hospices and 75 percent of all home health agencies. Facilities and providers observed deficient on past surveys will be subject to follow up surveys to ensure that appropriate corrective actions have been taken.

## Administrative Costs

HCFA's FY 1989 budget request for administrative costs is $271 million, a 7.1 percent increase over expected FY 1988 spending. This amount, which represents 0.2 percent of HCFA's total outlays, is needed to support HCFA's workforce (personnel compensation, rent, postage, telephones, travel, supplies, training); to continue our efforts to upgrade information systems management; and to fund contracts that are essential for program reviews and analyses. Our budget request would support a staffing level of 4,046 FTEs. Most of the new FTEs requested will be needed to assume the Medicare hearings and appeals function in FY 1989. The remaining FTEs are needed to restore HCFA staffing to what we feel is the minimum that will permit us to carry out our legislative mandates and management initiatives.

Although the figures cited above include our expected needs for funds and staff only under current law, we have also requested establishment of a catastrophic health insurance contingency fund of $112 million. This money would become available upon enactment of catastrophic legislation and would be used to set up a sophisticated tracking system to coordinate payments, monitor when beneficiaries reach the benefit cap and to administer the drug benefit (if the Senate version of the bill were enacted). While these funds would be needed to cover administrative start-up costs in FY 1989, we assume that ongoing administrative costs (as well as benefit costs) would be covered in full by the new program's premium collections.

## Conclusion

During the past year, the Health Care Financing Administration marked the 10th anniversary of its founding in 1977. For an agency not yet in adolescence, HCFA has been tested and tried in a way that is perhaps unprecedented. Growing up during years of fiscal constraint, we have been unusually creative in seeking cost effective solutions to both administrative and programmatic problems. We implemented major new programs such as the Prospective Payment System and the Peer Review Organizations while reducing administrative overhead through extensive use of contracting authority, interagency and private sector cooperation, and automation.

The budget we present to you today is offered in that same spirit of creativity and vision tempered by pragmatism. We know that further modifications of the Medicare and Medicaid programs are inevitable and necessary over the years to come. We want to participate actively in that process and we believe that the principles of decentralization and use of market-based incentives hold out the most promise. While the Administration and Congress continue to work together to devise a workable long range strategy, HCFA needs a realistic level of funding in order to carry out its crucial day-to-day missions. The budget request I have described today would, in our view, give us sufficient resources to provide quality health care to Medicare and Medicaid beneficiaries in FY 1989 without wasting scarce administrative dollars. I know that you will give it serious consideration and I would be happy to respond to any questions that you may have at this time.

### INTRODUCTION OF ASSOCIATES

Dr. ROPER. Thank you, Senator, members of the subcommittee. I am pleased to be here. With me is Dennis Williams, Deputy Assistant Secretary for Management and Budget, Lee Mosedale who is Director of our Office of Financial Management and Procurement and Mr. Robert Streimer, Acting Associate Administrator for Management and Support Services.

### OVERVIEW OF FISCAL YEAR 1989 BUDGET REQUEST

As you said, I will summarize my statement. I would begin by saying that the health care system, Government programs, and private programs, is in the midst of profound change. We have seen fundamental changes in the way health care services are organized, delivered, and paid for and we in Medicare and Medicaid are undergoing the same rapid change. Frankly, there is no end in sight to that trend.

We have been subject to, quite properly, close congressional scrutiny as these sweeping changes have occurred. The Omnibus Budget Reconciliation Act of 1987 gave us a whole series of new changes to implement in Medicare and Medicaid. We are on the verge of new catastrophic health insurance protection in the Medicare program that the Congress appears about to pass.

The budget we present here today gives our vision for the future. We would like to move in the direction of a more decentralized system of management of the Medicare program with increased consumer choice and incentives for enhanced quality without utilization of services beyond what is necessary. The OBRA 1987 legislation reduced expected Medicare outlays and increased Medicare receipts by a total of $2.6 billion next fiscal year. We have several other changes in Medicare we believe are consistent with the December summit agreement.

Let me discuss in some detail the items which we request in the appropriated accounts administered by HCFA.

### GRANTS TO STATES FOR MEDICAID

First I will describe the grants to States for the Medicaid program. Medicaid will serve an estimated 25 million low-income persons this coming fiscal year. We are requesting $32.7 billion to fund benefits and administration of this Federal and State program in fiscal year 1989. That is a 6.7-percent increase above our current estimate for fiscal year 1988.

### PAYMENTS TO THE HEALTH CARE TRUST FUNDS

Next is the payments to health care trust funds. This account consists almost entirely of the Federal general revenue subsidy of the Supplementary Insurance Program, part B of Medicare. As you know, Federal general revenues finance 75 percent of program costs at the present time. Our fiscal year 1989 request for this account is $32.1 billion, which represents a 24-percent increase over the prior year. That very large increase is due to increased expenditures from part B of the Medicare program. We have a legislative proposal to extend the part B premium permanently at 25 percent of the aged program costs, which would slow the rate of increase in the payments account beginning in fiscal year 1990.

We believe one of the prime policy challenges facing both the administration and the Congress is how to deal with the very rapid growth in part B of Medicare. It is not a simple problem; it will not respond to simple solutions. A number of our research projects are looking at the question of physician payment under Medicare and we believe there are a number of promising alternatives. One of these is the idea of offering preferred provider organizations as an option for Medicare beneficiaries, much as the private sector is now doing for people under 65.

### PROGRAM MANAGEMENT

Through its program management accounts, HCFA oversees the administration of both Medicare and Medicaid, monitors the quality of services provided to beneficiaries, conducts relevant policy research and funds the claims processing and review activities of the fiscal intermediaries. We request for next fiscal year, $1.8 billion.

### RESEARCH

The sum of $32 million is to fund HCFA's research program, a tiny amount of money compared to the $117 billion that we will expend in health care outlays. Priorities for research in the coming year are, again, as I said, studies of physician payment issues, studies of postdischarge, after-hospital care needs of Medicare beneficiaries and studies of the cost and effectiveness of delivering care to victims of Alzheimer's disease.

### MEDICARE CONTRACTORS

A principal part of the administrative budget of HCFA is funding for the Medicare contractors. We are requesting a total of $1.4 billion to fund these contractors in the next fiscal year. That is a significant 24-percent increase over fiscal year 1988 and largely due to increasing claims processing costs. One of the requirements given us by last year's reconciliation bill is that we pay claims no faster than a given number of days and no slower than another specified number of days and it is going to be more costly to calibrate claims payment timeliness in this way.

Further, we are expanding our claims payments safeguard activities to make sure we are paying appropriately for appropriate services and we are investing in a number of productivity improvements in the Medicare contractors. We believe that these safeguard activities are important and that we can save a total of $3.5 billion in benefit outlays in the next fiscal year if audit and review activities are stepped up as we propose in this budget.

## STATE SURVEY AND CERTIFICATION

Through the State Survey and Certification Program HCFA ensures that facilities participating in Medicare and Medicaid meet certain quality and safety standards. We are requesting a total of $121 million for this activity next fiscal year. $55 million of this was included in the Medicaid total I provided earlier, an additional $66 million is needed for Medicare survey and certification. We believe that this is one of the most important quality safeguard activities we have to offer our beneficiaries.

## ADMINISTRATIVE COSTS

HCFA's fiscal year 1989 budget request for administrative costs is $271 million, a 7.1-percent increase over fiscal year 1988. This amount would support a staffing level of 4,046 full-time equivalent positions. We have also requested establishment of a catastrophic health insurance contingency fund of $112 million. This amount would become available upon enactment of catastrophic legislation and would be used to implement that legislation.

## CONCLUSION

In conclusion let me say that last year we celebrated our 10th anniversary as an agency. The Health Care Financing Administration is now about 11 years old. Much has changed in that short time period and much is changing day to day as we go forward. It is an exciting and challenging opportunity. We look forward to working with you in the future, as we have in the past and I will be pleased to answer your questions.

## RELEASE OF CONTRACTOR CONTINGENCY FUND

Senator CHILES. Dr. Roper, I understand that you have a new requirement for the last quarter of fiscal year 1988. Medicare contractors will be operating within a claims payment window of opportunity. Effective July 1, no claim can be paid before the 10th day and 95 percent of clean claims must be paid within the 26th day.

I understand, however, that 4 months after the 1988 continuing resolution, only $14.7 million or 26 percent of the $57.4 million contingency fund has been made available and that money will be needed to meet the prompt payment standard.

I also learned that OMB has now imposed this new offset, and will not release the remaining $42.7 million unless you match them in Medicare program cuts. How do we get around this sort of gridlock? It sounds like to me you have a pretty good plan but how are we going to get to the plan if the payers, the third-party people cannot get some funds so they can help you get to the plan?

Dr. ROPER. We are almost there. We are at the final stage of getting this remainder of the contingency fund. We have reached agreement with OMB. They agree with us that we need this money and we are on the verge of getting it. Today, I have talked to senior officials at OMB and I believe that we will have it very shortly.

Senator CHILES. Did you have to meet an offset and what did you do?

Dr. ROPER. Yes, sir.

Senator CHILES. What was your offset?

Dr. ROPER. Our proposed offset is to implement more quickly a series of things that we had already planned to do in the area of payment safeguards, that is, making sure that we are paying appropriately and not paying for things that we ought not be paying for.

Senator CHILES. Are you going to be able to do that?

Dr. ROPER. Yes, sir.

Senator CHILES. I would like to have you give me for the record what you have.

Dr. ROPER. I would be pleased to do that. We need this money. We have made that clear. Now OMB agrees with us that we need the money.

[The information follows:]

### REMAINDER OF CONTINGENCY FUNDS

The Medicare secondary payor [MSP] offsets accepted by the Office of Management and Budget in exchange for release of the remainder of the fiscal year 1988 Medicare contractor contingency funds consist of $40 million from hospital audits, $10 million from the implementation of HCFA's MSP regional data exchange systems, and $10 million from increased part B savings through outreach.

#### HOSPITAL AUDITS

In 1987, HCFA conducted a study which indicated that substantial Medicare secondary payer savings could be identified through the audit of hospital records. Over the course of the study, it was noted that at large hospitals, an average return of $50,000 was identified per facility review. Approximately 90 percent of the savings captured were related to inpatient confinements even though these accounted for only 30 percent of the records reviewed. Consequently, we decided to perform this audit nationally, using essentially the same audit protocol used in the original study, but significantly modifying the universe reviewed.

The scope of the audits will be limited to facilities exceeding 400 beds and to inpatient confinements. Within these constraints, we will review records for all known Medicare beneficiaires with certain high-risk characteristics.

#### MSP REGIONAL DATA EXCHANGE SYSTEMS [RDES]

HCFA discovered that Medicare contractors often were unaware of MSP situations which had been identified by another contractor. This lack of knowledge resulted in continued improper Medicare payments and failure to recover prior improper payments.

The RDES was designed to facilitate the sharing of current information on all MSP cases among all contractors. As with any new system, the RDES has had some minor bugs which require correction. We are currently preparing systems enhancements to purify the data base, and anticipate that updated and corrected information will be in place by midsummer.

### INCREASE PART B SAVINGS THROUGH OUTREACH

Although some attention has been directed toward physician education, most of the efforts of HCFA and its contractors to date have focused on hospital personnel. Additional resources will be focused on the physician community in the last half of fiscal year 1988. To assist the Medicare carriers in this effort, and to ensure the delivery of a consistent message, HCFA plans to develop and disseminate a package of MSP-related material that is directed at both the physicians and, more importantly, their billing personnel.

Our mailing will be targeted at participating physicians practicing specialties that most often treat Medicare beneficiaires. The mailing will be advertised in major trade journals to heighten expectations and awareness. HCFA will also direct carriers to perform followup outreach with their physician and office assistant communities to ensure the MSP messages are fully understood and accurately implemented.

Through these efforts, each carrier will identify new MSP cases for the beneficiaires it serves. Where erroneous primary payments were previously made, carriers will recover moneys owed.

### POSTAGE RATE INCREASE

Senator CHILES. As I understand it, the current year contractor budget does not include funding for the 3 cent postage rate increase that went into effect April 3. I have been told that an additional $5.6 million is necessary for that. That certainly would be another reason for the contingency funds being released at this time.

Dr. ROPER. Yes, sir.

### MEDICARE HEARINGS AND APPEALS PROCESS

Senator CHILES. The Budget Reconciliation Act of 1986 requires that a new appeals process before an administrative law judge be established for disputed Medicare part B claims that are more than $500. Last year the committee denied funding for a new staff of judges in the Health Care Financing Administration. At that time we felt we had not had a chance to review the need for HCFA to establish the new administrative law judge hearing process, independent from the Social Security Administration Medicare part A hearing process.

Since that time, we have asked the General Accounting Office to review your proposal. That review is being released today. Based on that review, we have some questions for you. Do you have a copy of that?

Dr. ROPER. My staff went over and looked at it last week but we have not received a copy of it yet.

Senator CHILES. I don't want to blind-side you.

Dr. ROPER. I am given to understand that I know what is in that report.

Senator CHILES. Good. I have that same understanding that I know, even though we got it today, too. [Laughter.]

Currently hearings and appeals from Medicare part B claims are conducted within the Social Security Administration. What is the difficulty in keeping those judges in Social Security Administration where they are currently located?

Dr. ROPER. I think a bit of history would be useful. As you may know, Medicare was administered by the Social Security Administration when the program was created in 1965. I mentioned in my opening comment that 11 years ago, in 1977, Medicare was moved out of Social Security; Medicaid was moved out of the welfare part of HHS and they were put together in a new agency, the Health Care Financing Administration. At that time, the only Medicare appeals function that was in place under law was part A appeals, a relatively small activity, and in the administrative decisions that Secretary Califano made, the decision was made to leave this appeals function in SSA.

Over the intervening 11 years, there have been many more complex appeals under Medicare, including the one added by OBRA 1986, a part B appeal right that will dramatically expand this activity. We believe it is now time to do what was not done 11 years ago and that is create an appeals function within the Health Care Financing Administration. To say that SSA ought to do HCFA's appeal work, that argument presented fully would be, I guess, we ought to do SSA's appeals work.

Senator CHILES. We will accept possession is nine-tenths of the law and they are now sitting with the judges. However, we have administrative law judges that are sitting in other places that we swap around all the time, but we decided that maybe it is better than housing them everywhere.

Dr. ROPER. That is a legitimate public policy argument, but I am simply saying this is going to be a major appeals function in the Government. We believe that we need people who are specifically trained and spend 100 percent of their time dealing with the complicated Medicare statute.

Senator CHILES. The real thing we are looking at here is your proposal. Whether your numbers are correct and the bottom line of your proposal is that Medicaid part B appeals will be handled quicker, cheaper, and more efficiently by you than by SSA. That is based on one judge, presumably in Baltimore, handling 50 cases per month, 600 cases a year, handling 1 case within 60 days as opposed to the current 198 days at Social Security and the average case costing $420 in expense as opposed to $900 currently.

GAO wonders about whether you are too optimistic of that as well as us in your budget request. You are asking $8.1 million for 154 full-time equivalent positions to implement the plan. My concern is whether we should test your model before we say that, OK, we are going to spend all of this money and anybody can sort of set, here is how we are going to do it, but whether things come out that way is something that we don't always know.

Dr. ROPER. I hear your point. We have done our projections carefully. I understand GAO questions our projections, but that is where we are.

### IMPLEMENTATION OF CATASTROPHIC HEALTH INSURANCE

Senator CHILES. The fiscal year 1989 budget request includes a $112.4 million contingency fund to be used to implement the catastrophic health program. As you know, Congress had expected to complete the bill and send it to the President by the Easter recess. It has not happened. Your budget assumes an implementation date of January 1, 1989.

Will you still need the $112.4 million if the implementation date slips, let's say to July 1, 1989?

Dr. ROPER. Yes, sir; we will the need the money.

Senator CHILES. Same amount?

Dr. ROPER. We would be glad to go back and look at the numbers. I am told that we need the same amount. The reason for that is that almost all of that money is for one-time costs, software changes in the way we oversee the program.

[The information follows:]

### CATASTROPHIC CONTINGENCY AMOUNT

Even if the effective date of the catastrophic insurance legislation changes, HCFA will still need the $112.4 million. These funds are essential for implementation and are primarily startup costs.

### BENEFICIARY EDUCATION

Senator CHILES. I wish you would look at that and see whether it would make any difference. Have you included any funds to educate beneficiaries about what is and what is not covered by the new program?

Dr. ROPER. Yes, sir; we have a very extensive beneficiary education campaign planned. In fact, we have gone so far as to tape the television public service announcements starring Secretary Bowen. Those are already in the can as they say. We are ready to go as soon as the Congress acts.

Senator CHILES. I am glad to hear that. Senator Mikulski.

### SPOUSAL IMPOVERISHMENT

Senator MIKULSKI. Thank you, Mr. Chairman, I just have a few questions. Dr. Roper, I would like to thank you for your continued cooperation in working on the spousal impoverishment issue which Congress is grappling with in the catastrophic health insurance bill, and is a little bit more delayed than we thought. But your input and advice on how we can achieve family responsibility without family bankruptcy has been very helpful and I am most grateful.

Dr. ROPER. I appreciate that. That is a very important issue and I am pleased that you have taken it on.

## SINGLE HEALTH CARE FINANCING ADMINISTRATION SITE

Senator MIKULSKI. I have a question first about the HCFA building. If the chairman had the good fortune to visit HCFA, he would see that in addition to your own main headquarters at the HCFA headquarters, many of your employees are spread throughout the Woodlawn area, often in makeshift buildings. Your predecessor's predecessor's predecessor, Dr. Carolyne Davis, was undertaking that and she viewed it as a very important issue in terms of morale, efficiency, management, delivery of services. Where are we on the HCFA building and does it still continue to be the problem that it was?

Dr. ROPER. It is still a problem. We have folks in 14 buildings and we would like to be in a single site for ease of operation, as you can imagine. We have recently come to an agreement with GSA to announce publicly our request for proposals on a single-site building in the Woodlawn area which is, as you know, where we are now located. We are doing that in an effort to look at the option of going to a single building. That will take some time to play out, but we are anxious to be about that.

Senator MIKULSKI. So, you have asked GSA to help you develop a plan?

Dr. ROPER. My understanding is GSA will shortly be announcing in public, however they do those things, a request for proposals back to GSA on such a building.

Senator MIKULSKI. We would like to work closely with you on this. Having visited some of those 14 sites, I think it is a tribute to your employees' dedication that they endure it and a real contribution of your maintenance people. I have seen it where they have held together computers and air-conditioning with bubble gum and baling wire and it is very difficult.

Dr. ROPER. Thank you.

## STAFFING OF PROVIDER REIMBURSEMENT REVIEW BOARD

Senator MIKULSKI. In terms of the provision of services, I would like to get to the issue, if I may, of the Provider Reimbursement Review Board. The chairman has raised some of the concerns about the administrative law judge issue. For the record, the Provider Reimbursement Review Board is a quasijudicial body attached to HCFA to resolve disputes between HCFA and health providers when there are claims for service.

I am told that the Provider Reimbursement Review Board is currently severely understaffed and that they function only with auxiliary typing contracts.

Could you tell us what is the situation with the Provider Reimbursement Review Board and what steps do we need to take to make sure that there is the adequacy of staffing there because I know this is an important conflict resolution mechanism that you have available to you.

Dr. ROPER. The Provider Reimbursement Review Board is the board that has been in place for many years that handles disputes overpayment, principally to hospitals under the cost reimbursement system that we no longer employ in Medicare. I make that point to say that it is handling disputes that arose in the period before 1983 when we began the new hospital payment system. It doesn't deal with disputes under prospective payment. In 1981, the PRRB as we call it, had 18 employees. It rose to 27 last year. It is currently staffed at 24. We have heard requests for more staff from that unit and we are evaluating those requests like we are from all other parts of the agency.

Senator MIKULSKI. How many staff do you currently have there?

Dr. ROPER. Twenty-four.

Senator MIKULSKI. You have 24. Do you have any idea of what you actually would need?

Dr. ROPER. We believe 24 is what we need to operate the PRRB.

Senator MIKULSKI. But people who run it say they need more. They have told you, haven't they?

Dr. ROPER. Yes, ma'am.

Senator MIKULSKI. Did they tell you what they needed?

Dr. ROPER. People all across the agency believe they would like to have more staff.

Senator MIKULSKI. Oh, we understand that. Did they tell you what they did need? Thirty-four people?

Dr. ROPER. I don't know. I would be glad to supply an answer for the record.

[The information follows:]

### PROVIDER REIMBURSEMENT REVIEW BOARD STAFFING LEVEL

In April 1987, the Provider Reimbursement Review Board requested a staff of 29 full-time positions.

### SECRETARIAL HIRING

Senator MIKULSKI. Mr. Chairman, I just have one other staffing question.

Dr. Roper, as you know, for more than 1 year we have been in conversation on the HCFA secretary shortage. I know you have permitted some management approaches to alleviate the tension like the mail pick up and so on which I think helped. But there are two issues in the secretarial shortage at HCFA.

One is the issue of your complying with this committee's report language. That is a larger policy issue. In correspondence and so on, it is your position that you do not have to follow, I am putting the secretary issue aside, let's talk about compliance with report language. Is it your position, Dr. Roper, that you do not have to comply with report language and view it as advisory to you? Could you clarify that?

Dr. ROPER. Sure. I am not a lawyer. I will ask my lawyers to help me.

Senator MIKULSKI. I am not trying to suck you into something here. I think it is very important in terms of our relationship with the executive branch, the way we actually use statutory language and the way, for flexibility, we use report language.

Dr. ROPER. My view of report language is that it is advice from the Congress that we ought to take very, very seriously.

Senator MIKULSKI. But you do not view it as mandatory or compulsory.

Dr. ROPER. I don't view it as legally binding. That is what statutory language is.

Senator MIKULSKI. I am not a lawyer either, but I have been advised that at least two U.S. court decisions, *UAW* v. *Donovan* and *Edwards* v. *Boeing*, that these cases say that if the report language is incorporated by reference in legislation, it has the force of law.

We are not going to resolve this at this hearing, but I think it is an important issue between the Congress and your agency and all agencies. I would really like your attorneys to review those two legal decisions and would like to bring this issue to the chairman's attention because I think, as you know, we use report language to provide flexibility and not really micromanage, we don't want to micromanage you or any other agency, but it enables us to provide direction or guidance without getting it into amending a statute.

Dr. ROPER. Yes, ma'am.

Senator MIKULSKI. Which we don't want to do. Mr. Chairman, I think you should be aware of this differing of opinion. That, of course, takes me to the 50 secretary issue and could you tell me the status of upgrading the clerical help that we felt was appropriate?

Dr. ROPER. Sure. We, since last summer, have added 21 secretaries in HCFA. We believe over the coming months, the remainder of this fiscal year 1988, we will add another 9, a total of 30 by the end of the fiscal year. We continue to look at personnel needs across the agency. FTE's are probably our most precious commodity and we are trying to meet all of the needs of our agency.

Senator MIKULSKI. Doctor, could you tell me how many of these 30 new secretaries are actually new positions or how many are replacements for people who have retired or left the agency since our first conversation on this?

Dr. ROPER. I will be glad to give you that. I don't have it at hand.

Senator MIKULSKI. What we were talking about is not replacements but add-ons.

Dr. ROPER. I would be glad to give you the numbers.

[The information follows:]

## SECRETARIAL HIRING

Our latest data reveal that since July 1987, HCFA has hired 46 secretaries and clerk typists at the central office. The number of hires exceeded—by 29—the number that left the agency. We plan to hire additional secretaries in places where such hiring is needed and consistent with automation efforts. This hiring strategy will continue, as the budget permits, until we reach an appropriate clerical/professional ratio.

MEDICAID COVERAGE OF CHILDREN AND PREGNANT WOMEN

Senator MIKULSKI. Thank you. Mr. Chairman, there are other questions but I think that essentially summarizes the thrust of my questions.

Senator CHILES. Thank you, ma'am. I know Senator Weicker has some questions for the record and I am going to have some, too, but I will ask you this.

Last year in the Reconciliation Act we contained a number of provisions of expanded Medicaid coverage. Among those were provisions to expand coverage to poor children and pregnant women and expanded coverage of health care to the homeless.

In reviewing the 1989 estimated number of recipients I see there is an increase of only 3.4 percent from last year. That is, the number of Medicaid recipients increases from 24.2 to 25 million. It seems to me it is critically important for States to provide new coverage if we are going to tackle the infant mortality program. Do you anticipate that the States will pick up this new coverage or are we going to have to make these benefits mandatory?

Dr. ROPER. I believe they ought to expand that coverage. That is why I went down to my home State of Alabama in January and, in concert with the Governor, urged the legislature to appropriate the State money so that we, the Federal Government, can match it to cover all women below the poverty line.

Senator CHILES. What did they do?

Dr. ROPER. They haven't done it yet. They are squabbling in the legislature over where to get the $6 million so we can give them $18 million match money. I think they will do it. I believe the principle of flexibility to the States is important but I am a pediatrician and believe the States very much ought to do this. Medicaid does work, it does provide better outcomes to pregnancy of poor women.

Senator CHILES. That is something that has to be looked at very strongly. I am coming to the view that we are going to have to mandate it. I thought the States would jump at the opportunity to cover this without having to do all of the expanded, cover all the beneficiaries, and especially the southern States where the numbers are so bad in regard to infant mortality, Governors in those States have been concerned about that, they took a lead in doing that in matching some of the revenues.

Dr. ROPER. If I could just add my point, which is related to the very matter you are raising. When I was giving this speech at Governor Hunt's invitation back in January, I said, listen, I am a Federal official. I argue back in Washington for flexibility to the States, but if you legislators don't do the right thing, I am going to lose that argument.

Senator CHILES. I did, too, but when I hear a State, like a wonderful State like Alabama, is fussing and trying to figure out where to get $6 million and you see those numbers in infant mortality and you know what the bottom line is, that the State and the Federal Government saves money if we provide that front-end care. That is just the bottom line.

Dr. Roper. It's infuriating. Yes, sir; as you well know from being a member of and author of the National Commission on Infant Mortality, it is a desperate need that we just have to deal with.

### CONTROL OF PART B COSTS

Senator Chiles. It certainly is. In January of this year Medicare part B premiums increased 38.5 percent, $17.90 to $24.80, the largest increase in the 22-year history of the program and yet in January 1989 under current law without catastrophic health insurance we expect the premium to increase $3.20 or 12.9 percent to $28. Depending on the final agreement reached on the catastrophic bill which may include some type of drug coverage, the additional premium could go from $3.60 to $5.

As you know, the beneficiary is paying 25 percent of that part B program and we are picking up 75 percent so we have seen our appropriations explode between 1987 and 1989. We jumped $11.4 billion or 55 percent from $20.7 to $32.1 billion. What do we need to do to contain this cost escalation?

Dr. Roper. As I said in my statement, it is a complicated issue, but I will give you a simple answer. I believe that we are going to have to develop information on what works in the practice of medicine and then encourage my physician colleagues to practice in a way that is cost effective. What that means in real words is we have got to get control of the doctors. Now, that will be difficult, it will be controversial, but I think we need to be about it. I would like to do it in a way that lodges most of that control in private organizations, not Federal bureaucrats like me.

What I mean is there is increasing reliance on private health plans like HMO's. We have had generally good experience across the country with such plans. You are well aware of one such plan in your State that we have not had good experience with. We are dealing with that. But I think that is the way we need to go over the longer haul.

Short of that, in the meanwhile we need to do things like a more intensive utilization review, which means our contractors looking over the shoulders of doctors and saying yes, we will pay for that and, no, we won't pay for that. Yes; you have to do this as an outpatient, no, you can't do it in the hospital. Utilization review costs money but it saves money over the long term.

I mentioned in my statement our desire to launch a series of demonstrations on preferred provider organizations, a technique that the private sector is now using. The common pathway in all of this is questioning decisions made by doctors for individual patients. A point I made in testimony last fall to the House Ways and Means Committee, I would just make again. What we are trying to do is find a way to lower the increase in expenditures.

## SAVINGS FROM PAYMENT SAFEGUARDS

Senator CHILES. You proposed to save $3.5 billion in benefit dollars in 1989 and the payment safeguards activities are funded.

Dr. ROPER. Yes, sir.

Senator CHILES. By my calculations, you could save $8.73 for every $1. How are we really going to measure those savings? Are we ever going to be able to measure those, because it keeps continuing to go up.

Dr. ROPER. The way we estimate those savings is by looking at individual contractors where we have spent extra money and measuring what has changed over the ensuing months as far as what they have paid for. We believe that those kind of patient safeguard expenditures pay off.

Senator CHILES. I think the most important thing you can do for your agency and for the future of people that come up with plans like this is to find some way of being able to show and convince the Congress that you have made these savings, whether they are $8 or $6 or $5, whatever they are.

We always hear numbers like this at the time you are seeking the money and I know they are well-meaning, but there never seems to be a way of really determining. Just like we had umpty-ump IRS agents and we say we put in a sum of money for that, we do that routinely in our budget and we, therefore, say well we credit ourselves with $3.5 billion. We are going to take in additional revenue. We don't have any idea in the world whether that happens or not, but we know that we have been doing it so often now that it bothers us all when we see somebody do it again. That is like waste, fraud, and abuse. We put an amendment on the floor and say I am going to spend so much here and we are going to crack down on waste, fraud, and abuse over here.

Dr. ROPER. I hear your point. The IRS can, a year down the road, find out how many of those new IRS agents audited returns that recouped some dollars; that is a knowable fact. In a similar way, we can, a year down the road, see how many more claims we disallowed.

Senator CHILES. What I am saying is that if you had really spent, set up a methodology and say here is how we are going to measure or while we calculate we will measure this based on now what these particular agencies are taking from us, what we are paying. We are going to use that methodology. Somebody like GAO would say, yes, this is a valid methodology and you would measure that. I think that would be of great help to the Congress. I know it would be a great help in seeking additional funds.

Dr. ROPER. I hear you; we will do that. If I could just make one further point. On the one hand what you are talking about is how we document our ability to constrain costs—to make payment safeguards to deny claims. I just have to point out that most of the time the message I get from Members of Congress is that we have denied claims and made beneficiaries mad and made health care providers like home care agencies and doctors mad and all I am saying is that that is both sides of the same coin. It is going to happen.

Senator CHILES. Routinely, it is about every 12 years for the public, it takes them a little while to just get a little bit, but we get somebody that runs for Governor in Florida and he says he is going to save $300 million. That is what used to be, that was in the old time, now they are going to save $1 billion. Then 2 or 3 years later somebody will ask him, why is it now the State budget is this much higher, how can you say you have saved it? He can always say, of course, it would have been $1 billion higher had I not invoked these savings.

Dr. ROPER. Yes, sir.

## ALZHEIMER'S DISEASE DEMONSTRATIONS

Senator CHILES. Dr. Roper, we consider Alzheimer's disease to be a major disease. We know it is only going to grow worse as our population ages. Many of the members of this committee, Senator Hatfield, Senator Mikulski, and I are deeply concerned about ramifications.

In the 1987 appropriations the committee provided $1.2 million for Alzheimer's disease respite care demonstration projects. Despite these demonstrations, they were supposed to study a range of options including in-home services, adult day care, and institutional care. How is it that we haven't gotten these demonstrations up and running?

Dr. ROPER. We are pushing ahead, sir. We will have three of these projects underway by the end of this calendar year. I share your and the committee's concern. My mother died of Alzheimer's disease.

Senator CHILES. Certainly, if it has touched you in that way, you do share.

Dr. ROPER. I recently politely reminded my staff of that fact and told them to get with it. We are going to move up the delivery date on this one.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. Thank you. I have some other questions, as do other members that you will be asked to answer for the record. Thank you.

Dr. ROPER. Thank you.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## FISCAL 1988 PROMPT PAY STANDARDS

Question. Dr. Roper, I understand that we have a new requirement for the last quarter of FY 1988. The Medicare contractors will be operating within a claims payment "window of opportunity." Effective July 1, 1988, no claim can be paid before the 10th day, and 95 percent of clean claims must be paid within 26 days.

We have been told that the Medicare contractors are having problems even now meeting the less stringent timeliness standards. For example, in February, 1988, 19 out of 50 carriers failed to meet the participating physician standard.

What needs to be done to improve this performance?

Answer. Recent experience indicates that performance is improving. In January, 35 of the 50 carriers failed the 19-day requirement, while 16 carriers failed the 26-day requirement. February statistics are better; they show 19 carriers failing the 19-day standard and 12 failing the 26-day standard. In March, 10 carriers failed the 19-day standard and 4 failed the 26-day standard. We fully intend to achieve the standards.

There are a variety of measures under current consideration that could impact positively on contractors' ability to meet both the maximum and minimum claims payment times. Examples of potential HCFA actions include: clarifying or revising existing claims processing instructions to reflect imposition of the claims processing floor and ceilings and ensure compliance with the requirements, modifying claims processing performance standards to monitor contractor performance against the floor and ceiling.

HCFA is currently engaged in a national study to identify the precise causes of the inability of some carriers to pay 95 percent of clean participating physician claims in 19 days. Based on the results of this study, HCFA will be better able to determine the appropriate action to take to improve claims processing timeliness performance.

## FISCAL 1989 PROMPT PAY STANDARDS

Question. The problem will only get worse.

For FY 1989, the prompt payment "window of opportunity" narrows. No claim can be paid before 14 days, and 95 percent of all clean claims must be paid within 25 days.

Dr. Roper, is your 1989 budget request of $739.2 million for claims processing adequate to meet these prompt payment requirements?

Answer. The complexity of the program, further compounded by the imposition of a floor, will significantly impact carrier operations. In FY 1989, the floor will be increased to 14 days and the ceiling for participating physicians will be lowered to 18 days. Requiring carriers in FY 1989 to hold claims for 14 days and reimburse participating physicians in 18 days will significantly increase operating costs. For FY 1989, the estimated costs for implementing this provision are $3.4 million for Part A and $17.9 million for Part B.

We believe, however, that our budget request of $739.2 million along with the recently released remaining contractor contingency fund in the amount of $42.7 million will provide sufficient funding to implement and meet the prompt payment requirements. (A portion of the contingency funds will be used to implement the floor provisions.)

## RELEASE OF CONTINGENCY FUND

Question. I understand -- four months after the 1988 Continuing Resolution has been signed -- that only $14.7 million, or 26 percent, of the $57.4 million contingency fund has been made available. This money will be needed to meet the prompt payment standards.

I've also learned that the Office of Management and Budget (OMB) has imposed new offset requirements; they will not release the remaining $42.7 million unless you match that in Medicare program cuts.

Dr. Roper, how do we get around this annual OMB roadblock in the future? Should we eliminate the contingency fund completely?

Answer. We reached closure with OMB on the payment safeguard offsets on April 21, when the remaining contingency of $42.7 million
was released.

The contingency fund should not be eliminated. The contingency fund has supplied the resources to respond to unexpected workloads and legislation. We have not budgeted for a contingency fund in FY 1989. However, I believe that a contingency fund would be appropriate in future years when we anticipate significant reconciliation legislation or unusually high and difficult to quantify workload increases.

## POSTAGE INCREASE NOT BUDGETED

Question. I also understand the current year contractor budget does not include funding for the three cents postage rate increase that went into effect on April 3rd. I've been told that is an additional $5.6 million. This is another reason we need the contingency funds released.

How are you handling that problem?

Answer. The $5.6 million required to handle the postage rate increase has been funded out of the FY 1988 contingency.

## ADMINISTRATIVE LAW JUDGES

Question. The Budget Reconciliation Act of 1986 requires that a new appeals process before an administrative law judge (ALJ) be established for disputed Medicare Part B claims that are more than $500.

Last year, this Committee denied funding for a new staff of administrative law judges in the Health Care Financing Administration (HCFA). At that time, we felt that we didn't have the chance to review the need for HCFA to establish a new administrative law judge hearing process that was independent from the current Social Security Administration Medicare Part A hearing process.

Since that time, we have asked the General Accounting Office (GAO) to review HCFA's proposal for this new administrative law judge unit. Based on that review, we have some questions for you, Dr. Roper.

## WHY NOT RETAIN JUDGES IN SOCIAL SECURITY ADMINISTRATION?

Currently, hearings and appeals for Medicare Part B claims are conducted within the Social Security Administration.

What's the difficulty in keeping the judges in the Social Security Administration where they are currently located?

Answer. The Omnibus Budget Reconciliation Act of 1986 (OBRA 1986) provided important new appeal rights for disputed Medicare Part B claims: the right to administrative law judge (ALJ) hearings when $500 or more is in controversy and the right to judicial review when $1000 or more remains in controversy.

In considering alternatives for implementing these new provisions, we focused on several objectives. Hearings must be fair and impartial to protect the due process rights of claimants. They should be prompt and as convenient as possible for all claimants, both beneficiaries and physicians or suppliers. The cost-effectiveness of the hearing process was also a factor. In designing a system to meet these goals, we determined that having Medicare Part B hearings and appeals conducted within the Social Security Administration would present several problematic issues.

Initially, I would point out the issue raised by the Energy and Commerce Committee (Report of the Committee on the Budget, House of Representatives, to accompany H.R. 5300, Report Number 99-727, July 31, 1986, pp. 96, 97) — Medicare expertise. Medicare cases, both Part A and Part B, constitute only a very small percentage of the hearings and appeals workload for the Social Security Administration's ALJs which fall unevenly across the nation. Consequently, Social Security's ALJs do not have the opportunity to develop the same expertise in handling Medicare cases that they do in handling their day-to-day Social Security disability workload. Placing the Medicare hearings and appeals function within the Health Care Financing Administration would allow and encourage the development of Medicare expertise by administrative law judges. Claimants would be the chief beneficiaries of this expertise through consistency in the decision-making process and more thorough handling of all issues.

A second consideration is the fact that the Social Security Administration's primary mission is to deal with its Social Security caseload. Currently, their office of hearings and appeals has over 150,000 cases pending and an average processing time of almost 200 days. Additional Medicare workload would diminish SSA's ability to provide timely service to both Social Security and Medicare beneficiaries. I believe Medicare beneficiaries should be entitled to much more timely resolution of their claims. Medicare beneficiaries deserve to have their hearings and appeals handled on a priority basis. This is not possible if the responsibility for Medicare hearings continues to rest with the Social Security Administration.

Finally, the Health Care Financing Administration believes that its proposed system will be able to handle Medicare hearings and appeals in a more cost-effective manner than the Social Security Administration is able to do within the context of the system it has devised for handling its primary mission of Social Security cases.

### GAO QUESTIONS COST EFFECTIVENESS

Question. It appears to us and to the GAO that your proposal is overly optimistic in a number of areas. The bottom line of your proposal is that Medicare Part B appeals will be handled quicker and cheaper by you than by the Social Security Administration.

First of all, your proposal assumes that 50 percent of all cases will be handled over the phone by voluntary agreement of the claimants. Secondly, you propose that at a central location, presumably Baltimore, each administrative law judge will (1) handle 50 cases per month (that is 600 cases per year), (2) handle a case within 60 days (as opposed to the current 198 days at Social Security), and (3) the average case will cost $420 in expenses (as opposed to the current $900 per case in Social Security).

I'm not so sure that your proposed appeals unit will be able to meet all of these performance standards. In your budget request, you are asking for $8.1 million and 154 full-time equivalent (FTE) positions to implement the new Medicare Part B administrative law judge (ALJ) appeals process.

Do you think we should test this administrative law model, to see if it works, before we go ahead full-throttle with this new process?

Answer. Despite our initial misgivings, as reported by GAO, concerning the practicality of doing a pilot, I have instructed the appropriate HCFA components to study the GAO recommendations and determine whether an appropriate pilot can be completed. In any event, Congressional action to provide funding would be necessary before the Health Care Financing Administration could undertake such an effort.

I would also like to point out that although cost-effectiveness should be a consideration in the placement of the Medicare hearings and appeals function, it should not be the principal consideration. As previously explained, there are other reasons which warrant placement of the Medicare hearings and appeals function within the Health Care Financing Administration regardless of whether the projected performance standards are met.

## CATASTROPHIC INSURANCE - CONTINGENCY FUND

Question. The FY 1989 budget request includes a $112.4 million contingency fund to be used to implement the catastrophic health program.

As you know, the Congress had expected to complete this bill and to send it to the President by the Easter recess. But that has not happened. Your budget request assumes an implementation date of January 1, 1989.

Will you need the full $112.4 million if the implementation date slips, say to July 1, 1989?

Answer. Even if the effective date of the catastrophic insurance legislation changes, HCFA will still need the $112.4 million. These funds are essential for implementation and are primarily startup costs.

Question. Have you included any funds to educate beneficiaries about what is and what is not covered by the new program?

Answer. Approximately $17.6 million dollars is built into the catastrophic contingency funds to prepare public service announcements and publish new Medicare Handbooks, pamphlets and press releases to educate beneficiaries and the public.

## CONSUMER REPORT ON NURSING HOMES

Question. For the last two years, your agency has released information on mortality data on a hospital by hospital basis for hospitals that treat Medicaid and Medicare patients. Many people have used this information to judge a hospital's "track record" against other hospitals in the local area.

I recently read that your agency plans to publish a similar report this summer on the quality of care provided by about 15,000 nursing homes.

I understand that a lot of people are concerned about this report, and that you don't have the level of support that you had with releasing the hospital data. How will the "quality of care" be measured?

Answer. On the contrary, the proposed release of nursing home information has even broader support than did hospital mortality. While there are some particular parties opposed, there is considerable support from consumer groups, nursing home industry representatives, and congressional staff. In March, HCFA sponsored an advisory group meeting to obtain broad based support and consensus on planning the nursing home information release. Advisory group participants included representatives from the industry, consumer groups, State government, the Department, and congressional staff. Subsequent to the initial meeting, committee members were polled on which indicators of quality (expressed in terms of several hundred program requirements taken from the long term care survey report form) were most important and reflective of the quality of care furnished by a participating facility. HCFA is currently tabulating the results and will present them to the advisory group at the next meeting. In the interim, we are continuing to consult with individual experts and these groups on numerous specific issues that will play a part in the release. We expect to obtain final consensus on the quality indicators and other issues such as distribution of the nursing home information in June.

## NUMBER OF MEDICAID RECIPIENTS

Question. Last year, the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) contained a number of provisions that expanded the Medicaid program. Among those provisions are expanded coverage for poor children and pregnant women, and expanded coverage of health care to the homeless.

Yet, in reviewing the FY 1989 estimated number of recipients, I see that there is an increase of only 3.4 percent from last year. That is, the number of Medicaid recipients increases from 24.2 million to 25 million. It seems to me that it is critically important for States to provide this new coverage if we are ever going to tackle the infant mortality problem.

Do you anticipate that the States will pick up this new coverage, or do we need to make these mandatory benefits?

Answer. As of March 16, 1988, 18 States include in their approved Medicaid plans infants under the OBRA 1986 poverty level option for pregnant women and children. Twelve States also include children over age one. We understand that additional States are considering including such groups under their Medicaid plans.

For OBRA 1987, it is too early for us to know how many additional States will elect to include these groups. The option of increasing income standards for pregnant women and infants is not effective until July 1988. The option for coverage of additional children over age 1 is not effective until October, 1988.

We believe in the principle of flexibility to the States. Most States require State legislative approval to expand their Medicaid programs. This may cause delays in adding these groups although States do intend to include such persons. We do not believe there is a need to consider mandated coverage.

## MEDICARE - PART B PREMIUM INCREASE

Question. In January of this year, the Medicare Part B premium increased 38.5 percent, from $17.90 to $24.80. This was the largest increase in the 22-year history of the Medicare program.

Again, on January 1, 1989, under current law, without catastrophic health coverage, we expect the premium will increase $3.20, or 12.9 percent, from $24.80 to $28.00.

Depending upon the final agreement reached on the catastrophic health bill, which may include some type of drug coverage, the additional premium amount ranges from $3.60 to $5.00.

As you know, the beneficiary is paying for 25 percent of the Part B program through these premiums. We appropriate the other 75 percent as a mandatory entitlement. So, we've seen our appropriations explode. Between 1987 and 1989, we jump $11.4 billion, or 55 percent, from $20.7 billion to $32.1 billion.

Dr. Roper, what do we need to do to contain this cost escalation?

Answer. Current law requires that the premium for Supplementary Medical Insurance be established at 25 percent of estimated aged program costs. The Omnibus Budget Reconciliation Act of 1987 (OBRA 1987) extended this provision through 1989. HCFA has proposed legislation to set the premium rate at 25 percent permanently.

The way to reduce increases in the Part B premium is to hold down program costs. In order to lower the rate of Part B spending, OBRA 1987 contained savings provisions that will reduce SMI outlays by a projected $11 billion for FY 1988 through 1993. In the FY 1989 budget, HCFA has proposed additional outlay savings for the FY 1989-1993 period of over $3.5 billion.

Our FY 1989 budget also addresses the need to increase the level of utilization review conducted by both the Peer Review Organizations and Medicare Part B carriers through increased funding for these activities.

We recognize that there is no single solution to rising physician payments. Past experience has shown us that fee freezes are often countered with increased utilization. We are looking at additional means for containing Part B expenditures, thus 40% of new research funds are proposed for the areas of physician payment and alternative payment systems.

In order to address the utilization issue, a demonstration involving Preferred Provider Organizations (PPOs) is being undertaken. We will also continue to promote Private Health Plan Options (PHPOs) as an alternative to fee-for-service. We believe that capitated payments to private health plans offer the greatest promise for slowing the growth of Part B expenditures. Capitation provides appropriate incentives to control both price and utilization.

Although we have not yet promulgated the premium for 1989 (which will happen prior to October 1, 1988), HCFA estimates that under current law the 1989 monthly premium will be $28.00. Our 1989 legislative proposals would reduce this amount to about $27.70. These estimates do not take into account the additional funds related to the catastrophic legislation now pending in Congress.

## RURAL HOSPITALS

Question. Dr. Roper, rural hospitals seem to be having a hard time operating under the Prospective Payment System (PPS). In 1980, 25 rural hospitals closed. In 1986, 41 closed, and in 1987, 40 closed. As a result, Americans living in 48 rural counties lack a local hospital.

Rural hospitals tend to have lower occupancy rates and higher operating costs. In order to meet these operating differences, the Congress mandated a 3 percent increase for fiscal 1988 rural hospital Medicare rates. That is nearly double the rate for urban hospitals.

This year, the Administration is proposing a 3.1 percent rate increase for rural hospitals (as opposed to a 2.6 percent increase for urban hospitals). Will these rate increases improve the outlook for rural hospitals?

Answer. There is evidence that rural hospitals have experienced financial difficulties, largely due to a combination of declining occupancy rates and an unstable economic environment. We, however, expect the statutory changes in the last two reconciliation bills, as well as the regulatory changes contained in the forthcoming FY 1989 PPS regulation, to improve the financial standing of rural hospitals. Of particular importance are the provisions which:

- Provide a higher PPS update for rural hospitals relative to those specified for urban hospitals.

- Expand the swing-bed program in order that rural hospitals with less than 100 beds can participate.

- Lower the threshold for classification as a rural referral center to rural hospitals with more than 275 beds.

- Provide for PPS payments equal to either 100 percent of the national rate or the sum of 85 percent of the national rate and 15 percent of the applicable regional rate, whichever is higher.

HCFA will continue to work with the HHS Office of Rural Health to monitor the status of rural providers, conduct research, and examine policies related to rural hospitals.

### PAYMENT SAFEGUARD INCREASES

Question. The budget request for fiscal year 1989 includes $403.1 million for payment safeguard activities, such as new prepayment medical reviews of high dollar and frequently performed services, and postpayment review of doctors with significant Medicare income increases. This is a substantial increase of $103 million, or 34 percent, over last year's appropriation of $300.1 million.

You propose to save $3.5 billion in benefit dollars in fiscal year 1989 if these payment safeguard activities are funded. By my calculations, that means for each dollar expended for payment safeguards, you expect to see $8.73 in benefit dollars saved.

Frankly, all we have seen are enormous increases in the Medicare program. How sure are you that these payment safeguard activities will result in $3.5 billion in savings?

Answer. In FY 1987, HCFA conducted independent audits of reported Payment Safeguard savings to determine the accuracy of contractor findings. Seven contractor sites were chosen for testing and audited by their regular CPA firms. The sites tested were Prudential (Part A and Part B Operations), Travelers (Part A and B Operations), Pennsylvania Blue Shield, California Blue Cross, California Blue Shield, Michigan Blue Cross and Blue Shield, and Blue Cross of Western Pennsylvania. These contractors represent about 21 percent of the national combined total of the Parts A and B benefit payments and about 19 percent and 28 percent of the separate Part A and Part B totals, respectively.

These independent audits results confirm the accuracy of the savings data reported to HCFA by the contractors. We fully expect to achieve the projected savings.

## ALZHEIMER'S DISEASE RESPITE PROJECTS

Question. Dr. Roper, we consider Alzheimer's Disease to be a major disease that will only grow worse as our population ages. This is not an interest that I alone have. Both Senator Hatfield and Senator Mikulski are deeply concerned about the ramifications of this disease.

In fiscal 1987 appropriations, this Committee provided $1.2 million for Alzheimer's Disease respite care demonstration projects. These demonstrations were supposed to study a range of options including in-home services, adult day care and institutional care.

How is it that we haven't got these demonstrations up and running?

Answer. The demonstration project is currently being developed. In September 1987, HCFA awarded a contract to Mathematical Policy Research, Inc. (MPR), to develop the demonstration design and an evaluation strategy. MPR also will assist HCFA in selecting 5-10 demonstration sites. The demonstration design and site selection processes should be completed by the fall of 1988.

## RESEARCH AND DEMONSTRATION BUDGET

Question. The FY 1989 budget request includes $32 million for your agency's research, demonstration and evaluation activities. This represents an increase of $5.2 million or 19 percent over last year's appropriation of $26.8 million.

Can you tell us what real achievements we can expect from your ongoing activities and the proposed 19 percent increase?

Answer. Current and future studies include quality issues, global fees, RVS, overpriced procedures, and medical effectiveness.

- Research underway on global fees, relative value studies, diagnostic tests, assistants at surgery, consultations and geographic practice cost differentials will serve as the basis for reforming Part B physician payments, one of the fastest growing spending areas.

- ORD research and demonstrations on cost and medical effectiveness of preventive services, flu vaccine, Alzheimer's disease, and nutritional therapy could result in a more effective Medicare benefit structure.

- Quality of care studies of both the Medicare and Medicaid programs will provide information on the impacts of these programs on the health status of program beneficiaries.

- Studies of the cost and quality of post-acute care services, research on casemix measures for nursing homes, and studies focusing on specific long-term care populations such as AIDS patients and the mentally retarded will provide the basis for both better understanding and reforming the financing and delivery of long-term care services.

## STATE CERTIFICATION

Question. The State certification program ensures that institutions and agencies providing health care services to Medicare and Medicaid beneficiaries meet Federal standards for health care quality and safety.

The FY 1989 request reduces contract support by $4.3 million, from $7.9 million to $3.6 million. With the decrease in funding for these contract activities, will the Health Care Financing Administration (HCFA) reduce its oversight responsibilities for health care quality and safety?

Answer. No, we will not reduce our oversight responsibilities for health care quality and safety. The contract support budget will fund reviews of 100 percent of the Psychiatric Hospitals, which includes an increase of 5.8 percent over FY 1988. Our request for direct survey activities will fund surveys for an additional 1,200 facilities and will provide a 4.1 percent mandatory cost-of-living increase for State Surveyors.

## CUTS IN HOME HEALTH VISIT SURVEYS

Question. The number of Home Health Agency (HHA) home visit surveys is being cut in half from 8,165 surveys in 1988 to 4,098 surveys in 1989. Generally, we're concerned that these cuts will reduce the certification activity necessary to insure health care quality and safety.

How do you justify reducing this program in view of our shared concern to monitor the quality of care?

Answer. HCFA devoted an enormous amount of attention to the HHA program in 1986 and 1987 due to the voluminous increase in participating facilities. During this time, when the HHA home visit program was initiated, the goal was to review approximately a third of the HHAs and visit approximately five beneficiaries from each HHA. The number of HHAs that have been participating will be leveling off in 1988 and 1989.

Now, based on our historical experience in conducting home visits, we have determined that a lesser sampling (to 20 percent and three beneficiaries of each) is sufficient to determine whether HHAs are providing quality paid-for care. Therefore, the workload volume will be concomitantly reduced.

## SECRETARY SHORTAGE

Question. Senator Mikulski has been concerned that a secretary shortage has affected the efficient functioning of the Health Care Financing Administration (HCFA) Woodlawn facility in Baltimore County, Maryland. As a result, the Committee directed Dr. Roper to report to us on the status of hiring 50 additional secretaries or clerk typists.

In a March 17 letter to this Committee, Dr. Roper, you stated that HCFA hired 21 secretaries between July and October, 1987. You anticipate an additional 8 or 9 secretaries will be hired by October, 1988.

What are your plans for hiring the additional 20 secretaries?

Answer. Our latest data reveals that since July 1987, HCFA has hired 46 secretaries and clerk-typists at central office. The number of hires exceeded--by 29--the number that left the Agency. We plan to hire additional secretaries in places where such hiring is needed and consistent with automation efforts. This hiring strategy will continue, as the budget permits, until we reach an appropriate clerical/professional ratio.

## NO MEDICARE CONTRACTOR CONTINGENCY FUND FISCAL YEAR 1989

Question. For the past several years, the Administration has requested, and the Congress has appropriated, funds for a Medicare contractor contingency fund. We believe the fund is necessary to avoid unanticipated program disruptions, and the need for program supplementals. As you know, it is very difficult for us to deliver supplementals on time to meet crisis situations.

Why haven't you requested any contingency fund for fiscal year 1989?

Answer. HCFA's request includes a contingency fund of $112.4 million for administering the catastrophic health insurance program. This contingency fund will be used for both Federal administration and contractors' costs if catastrophic health insurance is enacted.

In recent years, the contractor contingency fund has been used primarily to fund increased costs to implement new legislation. Because of the budget summit agreement, we assume that the only major new legislation which will be enacted in FY 1989 will be catastrophic health insurance. Therefore, we believe that this contingency will cover our unanticipated needs.

## CASELOAD PROJECTIONS

Question. In their study, the GAO indicates that you projected 7,000 cases for Part A and 17,000 cases for Part B.

Realizing that only a few claimants (200) have requested an administrative law judge (ALJ) hearing, what certainty do you have that 17,000 claimants will request an ALJ hearing under the new Part B procedure?

Answer. Admittedly, we do not know exactly how many Part B claimants will ultimately request ALJ hearings; however, that workload is just now starting to develop. Further, because of the case aggregation permitted under section 1869(b)(2) of the Act, many of the requests for hearing we have received are for claims on behalf of multiple beneficiaries. For example, the first 290 Part B hearing requests received actually seek hearings on 2,497 individual beneficiary claims. These multiple beneficiary cases were filed by physicians or suppliers; however, the individual beneficiaries involved could have filed individual hearing requests if they had wished to do so. Due to such situations, it is difficult to project the official number of "cases" which will be heard.

Nevertheless, the Part A workload has grown faster than we originally projected. SSA has received over 6,000 hearings during the first half of FY 1988, which is more than they received in all of FY 1986. Ultimately, I believe our original projection of a 24,000 case Medicare workload will prove fairly accurate over a period of time.

Question. What has been your experience for the last three years for the number of Medicare claimants requesting further review because of Medicare denials?

Answer. Our experience with requests for review of Medicare denials is reflected in the following chart:

MEDICARE APPEAL DATA

| | FY 1986 | FY 1987 | 6-Mo. FY 1988 |
|---|---|---|---|
| Part B Appeal Requests: | | | |
| Review Requests: | 4,599,021 | 5,424,799 | 2,585,490 |
| Carrier Hearing Requests: | 40,634 | 51,783 | 32,138 |
| ALJ Hearing Requests: | — | — | 398 |
| Part A Appeal Requests: | | | |
| Reconsideration Requests: | Unavailable | 89,052 | 37,264 |
| ALJ Hearing Requests: | 5,382 | 8,199 | 6,399 |

## TELEPHONE HEARINGS

Question. GAO has told us that your proposal assumes that Medicare Part B claimants will accept handling of their cases over the telephone. Even though "phone hearings" are considered voluntary on part of the claimant, you assume that 50 percent of the cases will be handled by phone.

What is the basis for this assumption?

Answer. Our assumption in this area is based on the success of the carrier telephone hearing option and our belief that telephone hearings will offer significant advantages to many claimants. During a survey that HCFA conducted last year, 29 carriers reported holding telephone hearings and 13 carriers reported that over 50 percent of their hearings were conducted by telephone. The Department's Inspector General is currently conducting the Secretary's study of telephone hearings as required by Congress (Omnibus Budget Reconciliation Act of 1987, section 4037). I expect that report to document further the success of telephone hearings at the carrier level.

I believe that our telephone hearing option will improve access to the hearing process for many claimants. Many beneficiaries, particularly the physically frail or disabled, will find telephone hearings less stressful and more convenient than attending a hearing in person at some location outside of their home. We expect most Part B hearing requests to be filed by physicians and suppliers, for whom the use of telephone hearings will generally be more convenient and less costly.

Question. What is your back-up position if 50 percent of the claimants do not accept telephone hearings?

Answer. We are reviewing this question, but believe that regardless of the percentage of claimants who opt for telephone hearings, the process we are proposing is still the most appropriate method of providing ALJ hearings to Medicare claimants. Our process protects the due process rights of claimants, provides convenient and prompt service to claimants, and is as efficient as possible.

## COST-EFFECTIVENESS OF CENTRAL LOCATION

Question. The GAO tells us that the cost-effectiveness of the telephone hearings assumes several factors. At a central location, presumably Baltimore, each administrative law judge will (1) handle 50 cases per month (that is 600 cases a year), (2) handle a case within 60 days (as opposed to the current 198 days at Social Security), and (3) the average case will cost $420 in expenses (as opposed to the current $900 per case in Social Security).

If less than 50 percent of the cases are heard over the phone, will this affect the cost-effectiveness of the central location concept for the hearings and appeals unit?

Answer. A lower percentage of telephone hearings will increase costs due to increased travel. What is not clear is the effect that a particular percentage decrease will have on the central location concept. This concept is based on more than the intention to hold some hearings by telephone.

Our expectation that each administrative law judge will be able to handle 50 cases per month is based on the historic productivity levels of Social Security's administrative law judges. If we are not able to conduct any hearings by telephone, because of the extensive travel that would be required, that level of productivity may be difficult to maintain for the long term.

Question. Do you have a minimum level of telephone acceptance, which is less than 50 percent, that will still allow you to maintain your central operation concept?

Answer. We do not have a minimum level of telephone acceptance that would allow us to maintain the central operation concept. We believe it is the most efficient operating concept for our initial efforts. The proposed centralized system is enhanced by the use of telephone hearings but is not dependent on them.

Several other factors contributed to the decision to use a centralized location. A centralized location allows greater flexibility and a more immediate response to any fluctuation in the geographic location of the workload. Additionally, it allows more efficient use of support staff, greater ease in meeting training needs, and a more consistent approach in dealing with various Health Care Financing Administration components if difficulties arise with prompt delivery of case files, inadequate documentation in a particular type of case, or other matters which could affect the ALJ unit's ability to provide prompt hearings and decisions.

We expect to evaluate our experiences concerning the caseload in various geographic areas and do not rule out the possibility of some degree of decentralization in the future.

Question. How did you calculate the average $420 cost per case?

Answer. The $420 cost per case reported by GAO was determined by dividing our budget for an organization with the capacity to handle 24,000 Medicare benefit claims annually by that number. The figure includes salary and expenses for ALJs, their support staff, and management and administrative overhead. Long distance telephone services and travel expenses were estimated based on our 50 percent telephone hearing assumption.

## TIME LAPSE FOR HEARING

Question. You say that Medicare Part B claimants can choose a telephone or face-to-face hearing before an administrative law judge.

Will it take the same amount of time to have your case heard, regardless if you request a face-to-face hearing or a phone hearing?

Answer. I believe that every Medicare claimant is entitled to a timely hearing decision. To that end, I established a processing goal of 60 days from hearing request to decision. To meet our goal, each case will have to be processed as quickly as possible.

We expect that telephone hearings may take place somewhat more rapidly than face-to-face hearings since scheduling difficulties will be fewer for both the claimant and the administrative law judge. Neither the claimant nor the administrative law judge will have to allow time for travel or interrupt other activities for more than the time required for the actual hearing.

Question. If that isn't the case, would the different handling times pre-dispose a claimant to choose one type of hearing over the other?

Answer. We do not believe that any small difference in processing times will tend to pre-dispose claimants to choose one type of hearing over the other.

First, the fact that some hearings will be held by telephone will improve the Agency's overall efficiency, thereby resulting in more rapid processing of all cases than if a face-to-face hearing were the only available option. Second, we believe that the cost-effective use of a busy beneficiary, provider, or practitioner's time or physical convenience for a claimant is more likely to prompt that individual to request a telephone hearing than any difference in scheduling dates.

Finally, we do not believe that claimants who wish to use the telephone hearing option, for whatever reason, should be deprived of that option as long as the telephone hearing process incorporates safeguards to ensure that all due process requirements are met. We feel particularly strongly about this in light of the fact that on-the-record hearings, which provide a much lower level of participation than telephone hearings, have routinely been permitted for the Medicare cases handled by the Social Security Administration.

## JUDGES

Question. Some fears have been expressed that your agency will unduly influence judges to decide case outcomes in favor of the Agency. One of the provisions of the Administrative Procedures Act protects administrative law judges (ALJs) from the bias of the parent Agency.

Will the ALJs be required to follow the Administrative Procedures Act?

Answer. Any hearings and appeals function within the Health Care Financing Administration will afford both claimants and administrative law judges the same Administrative Procedure Act protections that are available to Social Security claimants and administrative law judges. In fact, the statutory provisions of the Social Security Act which provide for hearings on disputed Medicare benefit claims provide for hearings by the Secretary to the same extent as the hearings provided for disputed disability or retirement claims.

Additionally, Health Care Financing Administration administrative law judges would receive the same protections as the administrative law judges employed by all other federal agencies. They would be hired from an Office of Personnel Management register, have life tenure, and not be subject to performance or appraisal reviews. They could be removed only for good cause after a hearing by the Merit Systems Protection Board.

Question. GAO informs us that other federal agencies use staff positions of GS-15 or higher for their administrative law judges. However, you are proposing to use the GS-14 level.

Why do you think it is important to have GS-14 judges for this hearing process?

Answer. I believe some misunderstanding exists concerning the Health Care Financing Administration's plans to use GS-14 administrative law judges. The Agency does not and cannot control or dictate the GS level of the administrative law judges it employs — the Office of Personnel Management determines the appropriate grade for these positions in accordance with published classification standards. In this case, the Office of Personnel Management has stated that the proper classification for the work to be performed in Medicare Part A and Part B cases is a GS-14.

As I understand it, classification of administrative law judge positions involves consideration of two major areas: level of responsibility and nature of the case or legal problem at issue. An administrative law judge's responsibility in Medicare Part A and B cases is considered to be of the highest level. However, the nature of the case or legal problem is considered to be at the lowest of the three possible rating levels. The combination of these two factors has resulted in the GS-14 classification in question.

Some of the factors considered in rating the nature of the case or legal problem include the amount in controversy and the impact of the decision. Medicare Part A and B cases generally involve discrete and relatively limited amounts of money (often no more than a few hundred to a few thousand dollars) and the impact of the case is limited to the individuals directly involved.

Question. The GAO review indicates that these judges will "specialize" in Medicare.

What do you mean by that?

Answer. The term "specialize" is used to differentiate the current situation from the proposed situation. Placement of the Medicare hearings and appeals function within the Health Care Financing Administration will automatically allow Agency administrative law judges to "specialize" in Medicare since such cases will constitute their entire workload.

Question. Is this different from the way in which the Social Security judges handle disability cases?

Answer. This "specialization" is similar to the way in which Social Security administrative law judges become experts in the handling of disability cases by virtue of their constant involvement in these cases.

## FIXED PRICE CONTRACTS

Question. In last year's budget justification for FY 1988, you proposed to increase fixed price contracts from $62 million to $88.3 million. However, on page 58 of this year's budget justification, $44.9 million was allocated to fixed price contracts.

For FY 1989, you are proposing to increase fixed price contracts from $44.9 million to $80.5 million. This represents a 79 percent increase over last year.

Would you explain the difference in the proposed and actual funding levels for fixed price contracts in FY 1988?

Answer. In FY 1988, the difference in proposed and actual funding are due to reversion of a fixed-price contract to a cost contract and the cancellation of a procurement for a fixed-price contract. Additionally, we reduced the planned procurements for poor-performing contractors from three to one.

Question. Briefly, why are you proposing a substantial increase in fixed price contracts in FY 1989?

Answer. For FY 1989, the increases noted can be attributed to our plans to conduct two procurements to replace weak performing contractors under the authority of Section 2326 of DEFRA. We are also planning several experiments under the Section 222 authority. Those actions, together with ongoing contracts comprise the $80.2 million for fixed-price contracts.

Question. How much do you estimate will be saved by awarding this level of fixed price contracts? How were the savings calculated?

Answer. We do not predict specific savings to result from the awarding of fixed-price contracts. While the prices associated with these contracts are almost always favorable, we believe the principal benefits originate in the incentive aspects of the contract terms. The fixed-price itself, together with the positive and negative incentive and damages, provide the incentive for better performance.

## TRI-STATE CARRIER CONTRACT

Question. On April 26, 1985, HHS awarded Blue Shield of Massachusetts a fixed-price contract to administer the Medicare program in Maine, New Hampshire, and Vermont. This was the eighth in a series of experimental price contracts for Medicare claims processing. HHS considered the negotiated price on this contract--$1.35 per claim--to represent a significant administrative cost savings and standard that could be used when negotiating with the program's cost contractors.

In an April 1986 report, however, GAO cautioned that this price may have been artificially low, representing a "buy in" rather than the true market price of quality claims processing. From the beginning the contractor was plagued by serious problems--lengthy delays in claims payments, payment errors, unacceptable phone service, and other problems. The contractor's performance has improved, but at a significant cost--the contractor increased staffing levels by about 76 percent from 105 persons to 185. The contractor also faces potential penalties for early poor performance.

The Tri-state contract period ends September 1988, and HHS is in the process of renegotiating with Blue Shield of Massachusetts.

What is the dollar amount of performance penalties assessed under the initial operational period of the Tri-state contract? How much of this amount has been collected?

Answer. $21,500 in liquidated damages has been assessed during the initial contract period. All of the damages have been collected.

Question. Will the penalty amounts, along with the significantly increased costs to the contractor, drive up the price of this contract for the next operational period?

Answer. The damages assessed should have no impact on the contract price for the extension year. The addition of staff by the contractor could result in an increase in operational costs for the next period. However, the negotiated price is expected to be favorable when compared to the other contractors' costs.

Question. What are the HHS and contractor target prices for renegotiating the Tri-state contract? How do the HHS and contractor target prices compare to the national average cost per claim under the cost reimbursement contracts?

Answer. Price negotiations are currently underway for the first contract extension year. Fixed-price contract prices have been below cost reimbursement contracts. The price for the Tri-State extension will be below the national average cost.

Question. In light of the history of serious disruptions of service to beneficiaries and providers under the experimental fixed-price contracts and downward trend in cost per claim under the cost-reimbursement contracts, does HHS still believe that fixed-price contracting is appropriate for Medicare claims processing?

Answer. Any disruption of services is caused by the transition from one contractor to another rather than the type of contract involved. We believe that contractor efficiency is a function of management efficiency. We continue to believe that where a contractor change is required, a fixed-price or other incentive type of contract is fully appropriate and desirable for the Medicare program. Our experience to date with competitively let contracts bears this out.

## SECONDARY PAYER SAVINGS

Question. To help control rising Medicare costs, health and accident insurers who provide medical coverage in addition to Medicare are required to pay beneficiary claims ahead of Medicare. As part of its contractor performance evaluation program, HCFA assigns each Medicare contractor a secondary payer savings goal. GAO has reported that contractors have little problem in reaching the assigned goals and that consequently, Medicare is still paying substantial amounts that other insurers should pay. The HHS IG has made similar reports.

What is HCFA doing to assure that the secondary payer savings goals used to evaluate contractor performance provide sufficient incentive to intermediaries and carriers to seek recoveries and avoid payment when beneficiaries are covered by other insurance?

Answer. In FY 1988, the contractor MSP savings goals became a stand-alone CPEP element. It is the only stand-alone CPEP element in FY 1988, and it likewise will be the single stand-alone element for FY 1989. If a contractor does not pass this element it will fail CPEP. We believe that this in itself will provide the contractor with incentive to improve performance.

Question. What other means has HCFA used to provide incentives to encourage Medicare contractors to maximize secondary payer savings?

Answer. In order to provide proper incentive to intermediaries and carriers, HCFA must provide assurance to those organizations that the goals are achievable. To that end, a joint HCFA contractor workgroup has been established to develop State-specific goals for each category of savings. These goals will be based on actuarial data specific to each State and thus should be more reliable than goals developed in previous years. With this assurance, we believe that contractors will have a greater incentive to pursue assigned goals.

We have also provided contractors with a data exchange system, which improves their ability to identify potential MSP situations and seek recoveries or avoid payments.

In addition, we have initiated an extensive educational campaign among beneficiaries, providers, physicians, employers and insurers. While this is not an incentive to contractors, it does increase the opportunity of contractors to avoid payments.

## STAFFING

Question. On page 94 of the budget justification, you request an additional staff complement of 217 full-time equivalent (FTE) positions.

How do you plan to allocate these staff positions?

Answer. Of the additional 217 FTEs requested, 154 are for the implementation of an administrative appeals process for Part B Medicare claims. The remaining 63 requested are to support HCFA's ongoing operations. Demands on the Agency have increased substantially as a result of Administration initiatives and new legislative requirements. The additional full-time positions will allow HCFA to recruit and hire the necessary staff to carry out its current and future program agenda.

Question. Does this increase include any staff to administer the catastrophic health care program?

Answer. No, the 217 FTEs do not include any staff associated with the catastrophic health care program. If catastrophic is enacted and the contingency fund is released, an additional 50 FTEs would be available for the implementation of catastrophic.

## PRISM - PERSONNEL REDUCTIONS

Question. During last year's House Appropriations Committee hearings, Dr. Roper referred to the $15,485,000 request for PRISM, which is HCFA's project to redesign its information systems. Although Dr. Roper indicated PRISM would allow for personnel reductions, he did not specify the number or timing of such reductions.

What is the specific nature of personnel reductions expected as a result of PRISM?

Answer. In essence PRISM will not reduce HCFA's personnel level, but will enable us to control the level of staff growth and, further, allow us to reallocate staff to areas which are in need of additional support.

Question. What types of positions will be reduced?

Answer. It is anticipated that HCFA will realize a reduced need for manual clerical functions and will realign our staffing pattern to meet our new requirements.

Question. In which years will the reductions actually occur?

Answer. As PRISM is currently scheduled for completion in 1990, we anticipate that a change in HCFA's staffing needs will coincide with the implementation.

Question. What is the magnitude of expected reductions?

Answer. As mentioned earlier, HCFA does not anticipate a reduction in staff resulting from the implementation of PRISM; however we do anticipate the ability to reallocate staffing needs within the agency.

## BENEFITS OF PRISM

Question. HCFA initiated ADP modernization planning in 1982. The ADP modernization project, named PRISM in 1985, is currently scheduled for completion in 1990. As of March 1988, HCFA officials estimated the overall cost of PRISM at approximately $54 million.

What has been the benefits resulting from HCFA's ADP modernization efforts to date?

Answer. HCFA has been implementing PRISM in stages so that areas with high priority functions can benefit from PRISM as soon as possible. To determine how effective this focused support has been, we have monitored the program areas and developed the following list of accomplishments from PRISM enhancements.

First, are the PRISM enhancements in the area of the Peer Review Organization program. Because there are a limited number of review dollars, HCFA must limit its review to a small percentage of cases. Personal computers (PCs) and expanded mainframe support have enabled HCFA to focus reviews on the cases with the highest probability of problems. Further expanded mainframe capacity allowed HCFA to develop the Hospital Mortality Rate Reports.

Second, in the area of Part B Reimbursement, PRISM funds were used to develop the Part B Medicare Data Base which was used to study certain Part B procedures.

Third, in the area of PPS rate setting, PRISM funds were used to develop more complete data sets (e.g., 100 percent inpatient billing files, rather than the previous 20 percent file, and the enhancements to the Medicare Hospital Cost Report Information System) which were used to develop proposals in the following areas: medical technology adjustment, reset the PPS Update Factor, direct and indirect medical education payments, Periodic Interim Payment (PIP)/disproportionate share hospitals, and splitting fixed and movable capital payments.

Fourth, in the area of hospital outpatient services, PRISM enhanced HCFA's ability to review Fiscal Intermediary operations by providing additional computer capacity and data storage. As a result HCFA was able to generate savings proposals in the following areas: mental health, cardiac rehabilitation services, and duplicate payments to a hospital for inpatient and outpatient services.

Fifth, the area of Medicare bill processing has improved through four efforts. Using PRISM funds, HCFA was able to transfer the Medicare Master Records to disk which permits direct access to the records. As a result, bills can now be processed on a first-in/first-out basis rather than by date of service, thereby eliminating systems adjustments. HCFA was able to integrate the Premium and Bill Files and eliminate discrepancies that can result in duplicate payments by HCFA and other agencies. The PRISM software enhancements contractor helped support the Common Working File project. This project is testing the benefit of establishing regional sites to handle Medicare query reply processing for both intermediaries and carriers. PRISM funds permitted the development of an on-line inquiry capability allowing HCFA central office components to review beneficiary records to answer inquiries, correct problems, or provide individual information.

Sixth, PRISM enhancements to Health Maintenance Organization (HMO) systems have provided a means of tracking the voluminous correspondence workload and have automated the calculation of capitation payments to enrolled HMOs on a periodic basis.

Question. What will be the benefits accruing to HCFA as PRISM progresses and after PRISM is completed?

Answer. HCFA expects to gain significant qualitative and quantitative benefits from PRISM. These benefits arise from improvements in accessibility and quality of data necessary to make major programmatic decisions; level of service to providers, contractors, and the public; and ease of maintenance and modification of ADP applications. Completion of the PRISM effort will assist HCFA in implementing additional legislative requirements as our staff size remains relatively stable. Increased productivity will also give HCFA the ability to explore new legislative or operational initiatives and recommend cost effective changes.

## ADP SUPPORT

Question. The Health Care Financing Administration (HCFA) has historically relied on the Social Security Administration (SSA) for ADP support. In recent years the relationship between HCFA and SSA has changed from total ADP reliance by HCFA on SSA, to where SSA now performs about 75 percent of HCFA's processing. HCFA officials have expressed dissatisfaction with SSA's responsiveness to servicing some HCFA-ADP needs.

How will HCFA's ADP modernization project affect HCFA's need for ADP support from SSA?

Answer. Since the beginning of the Medicare program, SSA has provided the computer capacity to support the maintenance of beneficiary records used for determining eligibility and deductible status. Since the early 1970's SSA has also provided data communications support to provide information from these beneficiary records to Medicare contractors for timely and appropriate processing of Medicare claims. Most of this ADP and data communications support has involved high-volume, batch operations with requests for information received by the end of one working day to be responded to by the morning of the next working day.

As a result of our efforts to modernize our systems by implementing current data base technology, HCFA's requirements have begun to change. Recently, more of our support needs are coinciding with SSA's own peak workload periods. This is likely to continue as we pursue our modernization efforts and address new legislative requirements such as prompt payment of Medicare claims and implementation of Catastrophic Coverage.

Question. What, if any, are HCFA's plans for achieving ADP independence from SSA?

Answer. As PRISM proceeds to implementation, HCFA is analyzing its long-term requirements for ADP support. Part of this analysis relates to those systems now supported at SSA, and senior SSA-ADP managers are being consulted on the level of support which may be available in the future.

To meet its future needs and to improve the level of control that Agency management has over critical processing, HCFA is considering ADP independence from SSA as one of its options.

## MEDICARE CONTRACTOR BUDGET FLEXIBILITY

Question. I understand HCFA has run a few demonstrations of providing Medicare fiscal intermediaries and carriers increased flexibility in allocating their budgets among the various activities that are performed. What is the status of these demonstrations? I understand that most contractors have only very limited authority to reallocate funds among various budget line items, yet they are held accountable for achieving very specific performance objectives. Wouldn't it make sense to increase budget flexibility as long as performance objectives are attained?

Answer. Under this experiment, participating contractors can use additional budget management flexibility to improve performance, efficiency and to respond to day-to-day problems. Restrictions on the transfer of funds between line items has been removed. Contractors are not, however, permitted to exceed their cumulative quarterly allotments.

Two intermediaries (Florida and Georgia Blue Cross) and two carriers (Group Health Incorporated and Washington Physicians Service) have been selected to participate in this experiment.

One of the purposes of this experiment is to test the effect of budget flexibility on our performance objectives. The participating contractors are expected to meet all Contractor Performance Evaluation Program (CPEP) and payment safeguard performance requirements, with some modifications where appropriate.

This experiment, which is expected to last two years, became operational in January 1988. We will complete evaluation of its first year sometime early in fiscal year 1989. It is thus premature to provide an analysis of these experiments.

## BENEFICIARY AND PROVIDER SERVICES

Question. Your budget requests a modest increase for beneficiary and provider services of $13 million. You indicate you intend to intensify medical review activities in an effort to control escalating costs. Moreover, the Medicare program is changing rapidly — last year alone over 100 legislative provisions were enacted. Will this increase for beneficiary and provider services be sufficient to educate beneficiaries and providers about Medicare program changes and to respond to the number of inquiries that can be expected?

Answer. Yes. This will be sufficient. The $13 million represents increases due to inflation and workload in the areas of professional relations and beneficiary communications, i.e., responding to beneficiary inquiries.

Medical review activities will be intensified, with $50 million in additional funds being requested for next year. Of that amount, we plan to allocate approximately $5 million to educate physicians on coverage and medical necessity. Thus, we are allocating a total of $18 million for informing providers and beneficiaries of program changes.

## BACKLOG OF RECONSIDERATION REQUESTS

Question. I understand the backlog of requests for reconsideration of Medicare fiscal intermediary and carrier initial decisions is growing. How much does your budget include to address this problem? Will this be sufficient to meet the new performance standards enacted in the 1987 Budget Reconciliation Act -- 66 percent of reconsiderations processed within 60 days and 90 percent in 90 days for home health, durable medical equipment, and extended care claims; and 95 percent of reviews of initial decisions of other Part B claims in 45 days?

Answer. I am pleased to report that our reconsideration backlog is decreasing. For example, at the end of fiscal year 1987, there were approximately 27,000 HHA reconsiderations pending. As of the end of March 1988, the number of cases pending was about 23,000. In response to OBRA 1987, we have requested an additional $6.6 million in our FY 1989 Budget. We requested $2.1 million from the contingency fund for the second half of this fiscal year to enable contractors to hire and train staff in anticipation of the new requirements. We expect to make significant strides in reducing all backlogs.

## COST ESTIMATES OF CONGRESSIONALLY-MANDATED PAYMENT FLOORS

Question. The Omnibus Budget Reconciliation Act of 1987 established a payment floor for Medicare claims whereby no payments would be made before 10 days after a claim is received for the last three months in FY 1988 and 14 days in FY 1989. How much do you estimate this provision will save in FY 1988 and FY 1989. How much will it cost to implement this "floor?" Please describe your assumptions for the record.

Answer. HCFA currently estimates that the establishment of a 10 day payment floor in FY 1988 and a 14 day floor in FY 1989 will achieve program savings of $530 million and $460 million in each of those years respectively. The residual savings expected for FY 1990 through FY 1992 are projected to be approximately $140 million per year assuming that the payment floor remains at 14 days indefinitely. The estimated cost of implementing these payment floors is $10.6 million in FY 1988 and $21.3 million in FY 1989.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### MEDICAID REIMBURSEMENT FOR "NON-MEDICAL SERVICES" IN ICFs/MR

Question. Dr. Roper, the HHS press release accompanying the FY '89 Budget states that "HHS would take administrative and regulatory action to assure that Federal payments are only for medical care and not for non-medical care in ICF/MRs. The Department would conduct audits, clearly define "special education" and revise current regulations to reflect the new definition in order to ensure that only medical services in an ICF/MR are covered by Medicaid." The Department estimated that $30 million in Medicaid funds would be saved as a result of this effort.

I remind you that in 1986, amendments were made to the Education of the Handicapped Act to clarify that the requirements of P.L. 94-142 should not be construed to permit the elimination from Medicaid coverage of health related services that would otherwise be covered except for the fact that they are included in a child's individualized education plan.

It seems to me that your proposal to conduct audits, redefine special education and revise regulations fly in the face of Congressional Action.

Can you tell me the status of your proposal?

Answer. It is not our intent to issue regulations that conflict with the requirements of the Education of the Handicapped Act of 1986. If that impression was given by the language of the press release, it is inaccurate. Our current project flows from earlier attempts to impose the longstanding Medicaid exclusion against payment for educational or vocational services in ICFs/MR. It is an attempt to write a regulation that described the exclusion in terms which enable it to be applied properly. While we do not believe that it will be inconsistent with current law or ongoing litigation, we are prepared to modify it appropriately if events occur which make changes necessary.

### STATE CERTIFICATION - PSYCHIATRIC HOSPITALS

Question. Dr. Roper, HCFA proposes a large cut in contract support for the State certification program in FY 89. While I understand a number of contracts are nearing completion and will not be renewed, does this account for the entire $4,313,000 cut?

Answer. Yes, it does.

Question. Are any of the contracts not being renewed because of budget constraints?

Answer. There are no contracts that are not being renewed due to budget constraints. We awarded contracts in FY 1988 to address outcome-oriented surveys and the development of a resident assessment tool for beneficiaries in nursing homes. These will continue to be monitored through FY 1989, and require no new funding.

Question. What are the contracts that will not be renewed in FY 1989?

Answer. There are none that were planned to be renewed in FY 1989.

Question. Are contract support funds used for the oversight of the two special conditions, staffing and medical records, that are used to certify psychiatric hospitals for participation in the Medicaid and Medicare programs?

Answer. That is correct. The contractor will be responsible for providing qualified mental health consultants, scheduling and conducting surveys, and providing expert technical assistance and consultation to providers, HCFA regional office staff, and State agencies.

Question. Your budget documents indicate that participating psychiatric hospitals will increase from 583 in 1988 to 617 in 1989. Given this increase, how can you absorb a cut of more than $4 million in contract support?

Answer. Our FY 1989 request for contract support funds is $3.6 million, which will go toward the oversight of the two special conditions (i.e., staffing and medical records) in psychiatric hospitals. With this amount, all of the 617 psychiatric hospitals will be surveyed for compliance with the conditions of participation in the Medicare/Medicaid programs.

Question. What percentage of all psychiatric hospitals did HCFA survey in 1988?

Answer. We are planning to survey all psychiatric hospitals participating in Medicare and Medicaid during FY 1988.

Question. What percentage will be surveyed in 1989?

Answer. We are planning to survey all psychiatric hospitals participating in Medicare and Medicaid during FY 1989.

Question. What do you mean in your budget justification when you say "Oversight of psychiatric hospitals will be appropriately maintained"?

Answer. By that we mean that all psychiatric hospitals participating in the Medicare/Medicaid programs will be surveyed. We have found that the number of participating psychiatric hospitals has been increasing substantially each year. This growth is attributed primarily to increased consumer and corporate awareness of needed alcohol and drug treatment centers together with discontinuation of the certification of need process in some States.

### ICF/MR CERTIFICATION AND FTE'S

Question. Dr. Roper, your budget justification provides the number of overall FTE positions proposed for FY 1989, but it does not break down the numbers assigned to the individual state certification programs.

How many FTE positions will be allocated to monitoring intermediate care facilities for the mentally retarded?

Answer. As a result of intense efforts in the identification of problem areas in past years, we have redirected some of our resources into other areas. Therefore, in FY 1989 twenty-eight Federal surveyors will conduct Federal "look behind" surveys of ICF/MR facilities. The purpose of these surveys is to assess State survey agency performance and to ensure compliance with Federal regulations.

Question. Does that number include developmental disability specialists?

Answer. Of the 28 Federal surveyors monitoring ICF/MR facilities, 17 are DD specialists which is higher than the 12 mandated by Congress.

Question. What are the FTE allocations for surveyors of all other categories of facilities and how does that compare to FY 88? How does that compare to FY 87?

Answer. In addition to the 28 surveyors assigned to ICF/MR facilities, there are approximately 82 Federal surveyors nationwide conducting Federal monitoring surveys of the other types of facilities. This compares to 114 surveyors in FY 1988 and 105 in FY 1987.

### AZT AND MEDICAID

Question. Dr. Roper, as I am sure you know, I was very concerned that when AZT was first licensed, 14 States did not cover the cost of this drug under their Medicaid program. While I recognize that these reimbursement decisions are made by the States, I would hope as the HCFA Administrator you would work with the States to encourage them to expand their programs to be sure such drugs are covered. Do you know, currently, how many States still do not cover AZT under their Medicaid plan?

Answer. Currently, all States and Territories (including Washington, D.C., and Puerto Rico) include AZT in their State Medicaid Formularies except for the following 5 States: Alabama, Arkansas, Colorado, Florida and Louisiana.

## AIDS/MEDICAID

Question. Dr. Roper, I understand the intragovernmental Task Force on AIDS Health Care Delivery recommended that HCFA convene a meeting of State Medicaid Directors to explore collaborative efforts related to health care needs of aids patients. Has such a meeting been convened?

Answer. No, not yet.

Question. If yes, what were the highlights of the meeting? If no, why not and when will that meeting convene?

Answer. Since the issuance of the Intragovernmental Task Force Report earlier this year, HCFA has been examining the options available to achieve the report's recommendation to promote communication and collaborative efforts of State Medicaid Directors and other State public health officials in the delivery of health care to AIDS patients. We have been exploring the most efficient and beneficial method to achieve this goal in order to reach the maximum audience.

Some of our options include holding one national conference or several smaller regional meetings or conferences. We have also been in touch with other organizations within the Federal government and in the private sector who are conducting AIDS conferences to co-sponsor a conference or to "piggyback" another national conference or meeting scheduled in the near future.

Question. Followup: Your budget justifications indicate that HCFA plans on continuing studies which determine the implications of AIDS for the Medicare and Medicaid programs. What kind of studies are you conducting?

Answer. The Health Care Financing Administration (HCFA) is playing a major role in providing health care services to AIDS patients under the Medicaid and Medicare programs. While the Federal government is a major payor for health care for AIDS patients, it is important to stress that State and local governments, the private sector and individual patients need to continue to share in meeting the financial costs of providing health care services to people with AIDS. The following activities have begun in HCFA to study program utilization and expenditures and the distribution of public and private participation in financing services for AIDS patients.

In an attempt to use data available at HCFA, a study using Tape-to-Tape data in California is underway. The Medicaid Tape-to-Tape project is an ongoing research effort that uses person level data on program enrollees, services, expenditures and providers. This study has used a set of specific ICD-9 codes representative of AIDS patients but rarely found in other patients, and validated the data file with the California Department of Health Services. The study focuses on males ages 18-50 with AIDS for 1981 through 1984. The changes in utilization and expenditures from Medicaid will be presented. Following this study, a longitudinal analysis of this population will be performed using California data from 1981-1986.

Also, HCFA has sponsored several other activities to study utilization and expenditures of persons with AIDS in the Medicaid and Medicare programs. Through the Rand Research Center, we provided for a study using available information from health services literature focusing on Medicaid costs of AIDS patients. As a follow-up project, Rand is developing a conceptual design and construction of a research database including information on AIDS pathology, treatment costs and intervention services. Also, the project will test the feasibility of the data collection and analysis approach by using a sample of AIDS patients in Los Angeles. This component of the study will result in findings on AIDS treatment costs and their financing in what is now the nation's third largest community of AIDS patients. Finally, it will construct a plan for combining data on AIDS costs and financing emerging from several independent sources across the nation. Many jurisdictions now have AIDS billing or charge studies underway. A survey of State AIDS and Medicaid agencies is being conducted to examine the possibilities of obtaining data from multi-state analysis.

Another study of the economic consequences of AIDS and ARC for the Medicare and Medicaid programs is being funded by HCFA and conducted by the George Washington University. The purpose of this study is to explore the potential consequences of AIDS for the Medicaid and Medicare programs over the next decade. The study will use the best currently available estimates of prevalence and cost per case and other selected variables to develop estimates of the portion of these costs that may be borne by Medicaid and Medicare. The project will provide concept papers focused on the cost implications for each of the Medicaid and Medicare programs and develop a methodology to estimate the effects of alternative scenarios of the development of AIDS cases, treatment modes and the distribution of sources of payment of expenditures.

Finally, a study of providing case management to persons with AIDS in San Francisco is being developed for the Fall issue of The Health Care Financing Review. In order to continue our work in the area of health services research on financing health care for AIDS patients, we will be soliciting for AIDS studies in our annual cooperative agreement/grants announcement.

Question. What are your findings?

Answer. The Medicare and Medicaid programs are together making an important contribution to the financing of health care services for persons with AIDS and HIV related illnesses. These broad-scale financing programs are accomplishing this principally within the same eligibility criteria and coverage provisions that apply to others in similar circumstances who can qualify for these programs, regardless of their disease or medical condition.

The Medicare program is estimated to serve about one percent of all persons with AIDS in the country and it meets a similar proportion of the total direct medical costs of AIDS. In fiscal year 1988, these expenditures are estimated to be $15 million. With the introduction of such drugs as AZT it is expected that lives of persons with AIDS may be lengthened and that many more may survive the current 24-month waiting period necessary to qualify for Medicare on the basis of disability.

The State-Federal Medicaid program plays a much larger role because of the demographic and economic characteristics of those with HIV infection, ARC and AIDS. An average 40 percent of all persons with AIDS nationally are estimated to be served by the Medicaid program. In some areas, especially those with large numbers of IV drug abusers, the percentage served by Medicaid rises as high as 65-75 percent. Medicaid meets about 25 percent of all direct medical care expenditures for persons with AIDS nationally. Medicaid State and Federal expenditures for this purpose are estimated to be $750 million in fiscal year 1988, including the costs of AZT, rising to an estimated $3.2 billion in fiscal year 1992. These costs are shared roughly 50-50 by State governments and the Federal government.

The estimated future expenditures under the Medicaid and Medicare programs are considerable; however, future projections of the number of cases and costs are dependent on many factors about which data are currently limited. These include prevalence rates of HIV infection among the population, especially those engaging in high risk behaviors like IV drug abuse; costs of new and developing therapies, sero-conversion in the organization of care. Both the Public Health Service and the Health Care Financing Administration are continually reviewing these factors and their effects on the number of AIDs cases, on delivery system needs, and on costs.

Using current projections, AIDS spending will still be only 4 percent of the Medicaid budget by fiscal year 1992. Even if the projections of medical care expenditures for persons with AIDS were to double by that date or later in the decade of the 90's Medicaid AIDS expenditures would still remain a relatively small fraction of total Medicaid expenditures, about 8 percent.

Although AIDS and HIV infection will continue to pose significant problems in terms of financial, human, and health delivery system consequences, there is no evidence that the costs of AIDS will overwhelm our health care system or our economy.

## MEDICARE CLAIMS REVIEW DELAYS

Question. A recent communication from an organization in Connecticut involved in assisting Medicare recipients through the Medicare appeals process has troubled me greatly. The letter concerns the long delays in the Medicare request for reconsideration and request for review process which have confronted many elderly beneficiaries in my State. Of particular concern is the devastating impact the delays have had on aged individuals who have been forced to go without needed health care while their claims are reexamined. One elderly recipient had to wait 239 days for the reconsideration decision. In the meantime, the organization that was providing home health care determined it was no longer able to "carry her case" and terminated her care.

The Omnibus Reconciliation Act of 1988 instructed the Secretary, beginning January 1, 1988 to evaluate fiscal intermediaries and carriers (those responsible for review) to see whether 66 percent of reconsiderations and reviews are decided within 60 days, and after 1989, whether 75 percent are decided within 60 days and 90 percent within 90 days. Given this expression of Congressional concern, what steps will be taken by HCFA to improve the response time for Medicare requests for reconsideration and requests for review?

Answer. We are aware that there have been delays. We have taken steps to improve performance and we plan more.

- o New performance standards as required by OBRA have been drafted and will be in place by October 1, 1988.
- o Several procedural revisions have been implemented which streamline and simplify the process without any diminution of due process.
- o Additional funds have been requested for contractor staff.

Question. Has HCFA done any recent evaluations of the length of time intermediaries and carriers are taking to process reconsiderations and reviews?

Answer. We have been evaluating contractor performance on an ongoing basis and annually as part of our Contractor Performance and Evaluation Program (CPEP). We have taken the steps mentioned previously to reduce processing times.

Question. The GAO found that requests for reconsideration rose over 100 percent and requests for reviews rose 20 percent. Between 1986 and 1987, do you anticipate further growth in these requests in FY 1988 and FY 1989 and what impact do you estimate this will have on service to Medicare beneficiaries?

Answer. We do not see anything on the horizon which would lead us to believe that the volume of appeals requests has stabilized. We do not, however, expect reconsideration requests to increase 100 percent. We are projecting a 20 to 25 percent increase. However despite the increase in the volume of reconsideration requests, it is important to note that our reconsideration backlog is actually decreasing.

Because of procedural streamlining and simplification initiatives, we expect that our contractors will be able to handle the additional workloads without a diminution in beneficiary services. The intent of these initiatives is to free-up contractor time to enable more time to be spent on adjudicatory activities.

These initiatives include:

- On-the-record hearings with the option for an additional in-person hearing.
- Shifting of developmental responsibilities to providers.
- Simplified decisions.
- Phase-out of informal levels of appeals.

## NON-ASSIGNED PHYSICIANS

Question. Dr. Roper, in late March I wrote you regarding a problem in Connecticut involving the State intermediary for Medicare and non-participating physicians who provide service on an unassigned basis. These physicians, who are providing services to Medicare beneficiaries, are having the services by the intermediaries as "medically unnecessary" which in their judgement clearly are necessary and they report further that the intermediary, has been unresponsive to appeals. Many physicians are claiming that the claims are being rejected or downgraded in an arbitrary manner and conclude they are being singled out because of their status as non-participating physicians. What is your judgement on a subtle coercion on nonparticipating physicians by intermediaries in this matter?

Answer. Effective October 1, 1987, under provisions in OBRA 1986, physicians were prohibited from billing Medicare beneficiaries if assignment was not accepted and the services were found by the Medicare carrier to be medically unnecessary. Historically, beneficiaries have had financial protection and the physician has been liable for medically unnecessary services if assignment was accepted. This provision simply extended this protection to unassigned claims.

Claims are subjected to the same medical review process and are reviewed using the same criteria, regardless of whether they are assigned or unassigned. Physicians are not being singled out because they are non-participants.

Question. Have you received other inquiries of this nature or is this an issue unique to Connecticut?

Answer. In response to physician reaction nationwide, HCFA is making a number of changes in the administration of this provision. On April 1, carriers began contacting physicians to obtain any additional medical documentation prior to denying a claim. HCFA and the American Medical Association are jointly working on materials to educate physicians about carrier medical review. HCFA is also revising the tone and content of notices sent to physicians and we have issued instructions to carriers further clarifying which denials are subject to this provision.

Question. When can I expect a response to my March letter?

Answer. You can expect a response to your letter on or before May 13.

ALZHEIMERS RESEARCH

Question. Dr. Roper, your written statement indicates a research priority for FY 1989 is to "study the cost and effectiveness of a demonstration providing comprehensive services for Medicare beneficiaries who are victims of Alzheimers disease". Does this study involve any participation of the scientists at the National Institute on Aging?

Answer. Although we are not working directly with the scientists at the National Institute on Aging (NIA) on our Medicare Alzheimer's Disease Demonstration, collaboration is occurring between our two agencies in a more general context. The Alzheimer's Disease and Related Dementias Services Research Act of 1986 established the Department of Health and Human Services' Council on Alzheimer's Disease to assist NIA, the National Institute of Mental Health (NIMH), and the National Center for Health Services Research and Health Care Technology Assessment (NCHSR/HCTA) in developing and coordinating plans for research. I have a designated representative who serves as a member on this Council. Close communication, sharing of information, and collective review of promising new directions in research are arranged through the Council mechanism.

Under this legislation, we have been authorized to prepare a plan which provides for a determination of:

- the types of services required by individuals with Alzheimer's disease and related dementias;
- the costs of providing these services; and
- the costs to the Medicare and Medicaid programs and to private health insurers.

To help us develop the design and evaluation plan for our own Alzheimer's Disease Demonstration, we established a Technical Advisory Panel composed of individuals with both clinical research and service delivery expertise. The knowledge and experience of this panel has been an invaluable resource in designing a demonstration which we think is both responsive to the legislation and sensitive to the needs of Alzheimer's patients and their families.

## LABORATORY PERSONNEL

Question. The issue of the quality of clinical laboratories has been getting a great deal of media attention recently. We have been hearing about PAP Mills and problems in recruiting and retaining trained personnel due to fears about the spread of AIDS. As I understand it, Medicare currently uses the Baccalaureate Degree as a method to assure that qualified personnel are employed in the independent laboratories.

Is it true that HCFA may eliminate personnel requirements for the independent laboratories?

Answer. The Secretary has not yet decided on the personnel requirements which will be proposed in the revised clinical laboratory requirements. We are planning, however, to emphasize duties and responsibilities of all staff in addition to whatever qualifications are proposed.

Question. Given all of the quality assurance problems that exist in these laboratories, how can HCFA justify any relaxation of personnel standards?

Answer. The clinical laboratory regulations now being developed do not relax the personnel standards. These regulations will stress outcome measures such as proficiency testing and quality assurance, and will require laboratory directors to be responsible for ensuring that the laboratory staff is competent to perform tests.

Question. How does HCFA propose to maintain quality personnel in the independent laboratories and how does it plan to address the broader quality assurance issues confronting the laboratories?

Answer. We are not aware that there is any shortage of qualified personnel to work in clinical laboratories. As we stated in our response to the previous question, the proposed clinical laboratory regulations will not relax the Medicare personnel standards.

HCFA plans to address the broader quality assurance issues confronting laboratories by:

- o promulgating a national uniform proficiency testing program as part of the proposed revisions of the clinical laboratory regulations;

- establishing a new quality assurance program that will require that a laboratory be responsible for the quality of its services and provide the laboratory with the flexibility to determine how best to assure quality; and
- updating current internal quality control requirements for each specialty and subspecialty, taking into consideration current and future technological advances, as well as new methods of quality assurance.

## QUESTION SUBMITTED BY SENATOR JAMES A. McCLURE

### MEDICAID CERTIFICATION STANDARDS - IDAHO SCHOOL

Question. For the past 13 months, the Idaho State School and Hospital (ISSH) in Nampa, Idaho, has been working to meet medicaid certification standards. Deficiencies were identified and have been corrected by the hiring of 114 additional workers, providing 8,000 hours of staff training, recruitment of professionals such as speech pathologists, occupational therapists and physical therapists and development of a plan for active treatment of ISSH residents. During this time, the State of Idaho has made it perfectly clear that they wanted to do everything necessary to correct any deficiencies at the facility. Although the facility has developed a plan for "active treatment", the Health Care Financing Administration did not provide a great deal of technical assistance in helping ISSH improve its operation. What assurances can HCFA offer that, should unanticipated future problems be identified, that HCFA will provide whatever technical assistance is necessary to help bring the facility up to standards?

Answer. The Idaho State School and Hospital (ISSH), a Medicaid-only ICF/MR, had been under a State-initiated adverse action since August, 1987. At that time, a joint State-Federal survey found that the facility failed to meet 53 standards, certain of which seriously limited capacity to provide care. After receiving an acceptable plan of correction, the State conducted a resurvey during the week of April 11 and found the facility to be in substantial compliance with the requirements.

Upon the State's request, HCFA's regional office has provided active assistance to ISSH during the process. HCFA staff have gone to the State Legislature to answer questions about the ICF/MR program and the survey findings at ISSH, and have met with numerous State officials to assist them in understanding the nature of the problems found. Should future problems be identified at ISSH, HCFA will continue to cooperate, as it has in the past, with giving that type of assistance. The facility is responsible for finding the means necessary to maintain compliance with Federal requirements.

## QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

### QUESTION ON PROPER TREATMENT OF PROS

Question. Dr. Roper, I solicit your view on whether PROs should, at some time in the future, be appropriated? Do you believe that it is appropriate for OMB and HHS to determine the level of funding for a program this size without Congressional oversight? Are there other alternatives to the appropriation process?

Answer. We believe that funding for PROs should be through the annual appropriations process, rather than through direct apportionment from the Medicare Trust Funds (as is currently done). The Office of Management and Budget also supports this position.

The size and cost of the PRO program have grown considerably since the original legislation was enacted six years ago. In view of the substantial cost of the program, it would be appropriate for elected officials to determine PRO activity and related funding levels, rather than to allow Executive agencies to continue to make such decisions.

The appropriations process would bring PRO funding under the congressional fiscal oversight process, would eliminate ambiguities concerning Gramm-Rudman-Hollings offsets, and would permit HCFA to seek additional funding to implement legislative changes to the program, when necessary, from Congress rather than through a reapportionment request.

### LEGAL REQUIREMENTS TO RELEASE CONTINGENCY

Question. HCFA's FY 1988 appropriation includes a contingency for unanticipated workloads and other specific circumstances. This seems like a good idea. It is useful to make resources readily available to keep Medicare running smoothly. With this contingency, HCFA does not have to request the highest possible appropriation; instead they are able to request the best estimate of the amount needed and have some extra set aside for the unanticipated.

However, in view of Gramm-Rudman and the Budget summit agreement, these contingencies pose an interesting dilemma. Outlays for these contingencies are not scored when the appropriation is made. The outlays are scored only after the contingency is used. Use of the contingency requires no Congressional action.

What is your view of the Administration's legal requirements for offsetting the estimated outlays if you decide to use the contingency?

Answer. Under the Emergency Deficit Control Reaffirmation Act of 1987, the Administration was required to submit a budget for FY 1988 that did not exceed a maximum deficit reduction amount as determined by Congress ($144 billion). Under section 242 of the Act, supplemental budget estimates and changes are also subject to remaining within the Congressionally-mandated deficit reduction target. Therefore, to the extent that such a budget was submitted and enacted by Congress for FY 1988, any increased spending (or changes) having an impact on that deficit target must be offset.

Question. Do these requirements vary if we are already at the Bipartisan Budget Summit's discretionary outlay cap, or if we are at the maximum Gramm-Rudman deficit level?

Answer. The requirements are the same for both situations.

Question. If different from their legal requirements, how does the Administration usually handle these situations?

Answer. The Administration requires that any request for funds representing unscored outlays be accompanied by an offset, preferably resulting from a regulation or a procedural change.

## HISTORICAL USE OF CONTINGENCY

Question. Please supply a table showing historically (since 1981) the contingency allowed by appropriation action, how much of this contingency was used and for what, and the proposed offsets, if any, (and if relevant, the Congressional action on these offsets).

Answer. Offsets were first required in FY 1987 after passage of the original Gramm-Rudman Hollings bill.

## CONTINGENCIES ALLOWED BY APPROPRIATION ACTION

| Fiscal Year | Contingency Requested (In millions) | Released | Action/Comments |
|---|---|---|---|
| 1989 | -0- | | |
| 1988 | $105.3 | $57.4 | $57.4 million was earmarked for Medicare contractors to implement provisions of OBRA 1987. (OMB released $14.7 million on 3/4/88 and the remaining $42.7 million on 4/21/88.) This was offset by savings in MSP. No Congressional action was required. $47.9 million is for the implementation of catastrophic, if enacted. |
| 1987 | 50.0 | 41.1 | For Medicare contractors. OMB released $41.1 million on 1/22/87 to provide for unanticipated claims volume. (NOTE: The offset figure is unavailable.) |
| 1986 | 15.0 | 14.4 | For Medicare contractors. The initial amount of $15 million was reduced by $645,000 as a result of the Balanced Budget and Emergency Deficit Control Act of 1985, P.L. 99-177. OMB released these funds on 5/20/86 to provide for unanticipated workloads. |
| 1985 | 20.0 | 20.0 | For Medicare contractors. Total amount was released by OMB to provide for unanticipated workloads not anticipated in the budget estimates. |
| 1984 | 25.0 | 0.0 | |
| 1983 | 20.0 | 0.0 | |
| 1982 | 20.0 | 20.0 | For Medicare contractors to provide for unanticipated workloads. |
| 1981 | 10.0 | 10.0 | For Medicare contractors to provide for unanticipated workloads. |

## SUBCOMMITTEE RECESS

Senator CHILES. The subcommittee will stand in recess until 9 a.m. tomorrow, Thursday, when we will meet in Dirksen 116 to hear from the Office of Assistant Secretary of Health and Centers for Disease Control.

Thank you.

[Whereupon, at 11:25 a.m., Wednesday, April 20, the subcommittee was recessed, to reconvene at 9 a.m., Thursday, April 21.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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THURSDAY, APRIL 21, 1988

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9:10 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lawton Chiles (chairman) presiding.

Present: Senators Chiles, Inouye, and Weicker.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### OFFICE OF THE ASSISTANT SECRETARY FOR HEALTH

### STATEMENT OF DR. ROBERT E. WINDOM, ASSISTANT SECRETARY FOR HEALTH

ACCOMPANIED BY:

- WILFORD J. FORBUSH, DEPUTY ASSISTANT SECRETARY FOR HEALTH OPERATIONS AND DIRECTOR, OFFICE OF MANAGEMENT
- DR. PETER J. FISCHINGER, ACQUIRED IMMUNE DEFICIENCY SYNDROME COORDINATOR
- W. HARELL LITTLE, CHIEF, BUDGET BRANCH, PUBLIC HEALTH SERVICE
- DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, NATIONAL INSTITUTES OF HEALTH
- DR. JAMES O. MASON, DIRECTOR, CENTERS FOR DISEASE CONTROL
- DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET

#### OPENING REMARKS

Senator CHILES. This morning the subcommittee will hear testimony in support of the budget request for the Office of the Assistant Secretary for Health and the Centers for Disease Control.

We are delighted to have Dr. Windom, the Assistant Secretary for Health, with us this morning. Like last year, we are going to take advantage of Dr. Windom's appearance to get a comprehensive update on AIDS from the perspective of all of the public health agencies.

We can take some encouragement from the fact that the HIV infection rate for military recruits, blood donors, and job corps applicants has remained level, and the infection rate among the heterosexual population is still at 4 percent.

The very real scare that AIDS might spread widely into the heterosexual population does not seem to be happening yet.

The 1989 AIDS request of $1.3 billion is a 37-percent increase above last year. Together with all AIDS requests from the Department of Defense, Veterans Administration, and other Federal agencies, as well as the projections for Medicaid and Medicare and the Social Security Administration, our total AIDS spending is expected to be $2.193 billion.

### PREPARED STATEMENT

Dr. Windom, we welcome you today. We will let Senator Weicker make his statement when he gets here, and ask you to proceed with your oral summary. Your full statement will be placed in the record.

[The statement follows:]

# STATEMENT OF DR. ROBERT E. WINDOM

I appreciate the opportunity to appear here today to discuss the FY 1989 budget request for the appropriations in the Office of the Assistant Secretary for Health (OASH) -- the AIDS Research and Education appropriation request of $1.3 billion, the Public Health Service (PHS) Management appropriation request of $194 million, and the Retirement Pay and Medical Benefits for Commissioned Officers appropriation request of $108 million.

## AIDS RESEARCH AND EDUCATION

As you well know, Mr. Chairman, AIDS is our number one public health priority. The request of $1.3 billion includes a 37 percent increase over FY 1988 and represents our best estimate of what is needed to maximize our battle against this disease.

The budget requests for AIDS have been consolidated in a single appropriation in FY 1989 in order to improve coordination, flexibility and visibility for the high level of resources being devoted to this top public health priority. Consolidating the AIDS funds will build upon the research and prevention flexibility available in FY 1988 to respond to scientific breakthroughs and unexpected crises as they occur. However, operational responsibility will continue to reside in the individual PHS agencies involved.

Consolidating funding for AIDS will enable me to more effectively manage the Department's AIDS efforts. In my role as Chairman of the PHS AIDS Executive Task Force, I oversee the development of the AIDS budget and ensure that our efforts are coordinated, that we explore every opportunity to prevent the further spread of this deadly virus, and that there is no duplication of efforts among the PHS agencies. I also serve as Chairman of the Federal Coordinating Committee on Information, Education and Risk Reduction that is comprised of representatives from the various Departments in the Federal government that have a role in the AIDS effort. As Chairman of the Committee I spearhead the coordinated effort of the entire Federal government in the battle against AIDS. I also chair the HHS Task Force on AIDS which meets weekly to improve coordination of the Department's battle against AIDS and to facilitate policy resolutions. One example of the many outcomes from these coordinated efforts is the Secretary's recent announcement of his Pediatric AIDS initiative.

In 1987, over 21,000 new cases of AIDS were reported, a 60 percent increase over 1986. In total, over 59,000 AIDS cases and more than 33,000 AIDS-related deaths in the U.S. have been reported to the Centers for Disease Control (CDC) since June 1981. There has been no documented case of recovery from fully developed AIDS. Each of the 50 states, the District of Columbia, Puerto Rico, the Virgin Islands, and the Trust Territories have reported cases of AIDS. In 1985, AIDS became the eleventh leading cause of potential years of life lost before the age of 65, and in 1986 it is expected to be eighth. As many as 1.5 million Americans may be infected with the AIDS virus already.

Mr. Chairman, in response to this menacing problem, the priorities of the Public Health Service are very clear. We will do everything we can to expand research and prevention activities to:

- Increase our knowledge and understanding of this disease - its origin and nature, genetic and biologic properties of isolated viral strains, individual susceptibility to infection, risk factors, various modes of transmission, and prevalence and incidence.
- Develop drugs and therapeutic products to care for those who are already infected.
- Develop vaccines to prevent the disease.
- Inform and educate the general public, school and college aged population, health care workers, and high risk populations (including minorities and IV drug abusers) to encourage individuals to minimize behavior that risks spreading or contracting the disease.

Mr. Chairman, extraordinary progress against AIDS has been made in a relatively short period of time, more than against any other complex new disease in the history of medicine. I would like to share with you some of our more recent accomplishments.

In the treatment area, various drugs and combinations of drugs are being studied both at the NIH and through the AIDS Clinical Trials Groups (ACTG) around the country. Under the ACTG program, NIH has established 18 Drug Treatment Evaluation Units and 17 Clinical Trial Units. Over 25 active research protocols are being conducted with an enrollment of over 3,200 patients. Also, NIH recently expanded its intramural capacity to conduct clinical research on AIDS patients through a new allocation of beds at the NIH Clinical Center for additional Phase I drug studies.

Azidothymidine (AZT) has been found to be effective in prolonging the lives of AIDS patients. The drug, now available by prescription, reduces the occurrence of life-threatening opportunistic infections and has been effective in treating the dementia seen in some AIDS patients. Another promising treatment being studied is a combination of AZT and a similar drug, dideoxycytidine, both pioneered as AIDS therapies at NIH. NIH has just begun a trial of trimetrexate as an experimental drug for treatment of pneumocystis carinii pneumonia patients who suffer serious adverse reactions to existing approved medicines. In addition, trimetrexate will be distributed as a "treatment investigational new drug" through the National Institute of Allergy and Infectious Diseases.

NIH has initiated a clinical trial to define a safe and effective dose of AZT for children. To overcome the problems of administering pills to small children, AZT is administered by continuous intravenous infusion via a belt-pack or a back-pack pump. The early results have been quite promising: the twelve children who have had either learning problems or some evidence of neurologic impairment because of AIDS have improved after receiving AZT.

More than eight new potential antiviral drugs entered clinical trials in the past year. In addition, thirty-five drugs or drug combinations are being reviewed for possible testing in the clinical setting. Six drugs entered testing for treatment of opportunistic infections, and several studies were initiated for AIDS-related malignancies. NIH is expanding its Preclinical Screening Program to examine 10,000 compounds annually, up from the current level of 3,000 annually.

Clinical trials of two experimental AIDS vaccines are currently in progress in the United States. In Phase I trials being conducted at the NIH Clinical Center and at our six Vaccine Evaluation Units located at university medical centers, the vaccine is being evaluated for safety and the ability to evoke an immune response. This is just the first of what we anticipate will be a number of candidate AIDS vaccines that will be considered for testing in the Vaccine Evaluation Units.

In the prevention area, several PHS agencies have been initiating new information and education programs and expanding existing programs to prevent the spread of this disease. The Centers for Disease Control has directed a national public information campaign for the Public Health Service; expanded HIV counseling and testing to health care settings serving high risk individuals, including IV drug abusers; initiated new programs for school and college-aged populations and minorities; and planned for an every household mailer to be distributed in June of this year. CDC has also begun a comprehensive program of HIV seroprevalence surveys that will provide important information on the spread of HIV infection in the general population. One of the many surveys being conducted is the neonatal surveys of childbearing women. CDC will conduct neonatal surveys in at least 25 states through anonymous testing of filter paper blood specimens routinely collected on newborn infants. Three states have already conducted over 60,000 such tests. The results of these tests will give us a new dimension of the infection rates in women of childbearing age and will provide a base for future predictions of pediatric AIDS.

The National Institute of Drug Abuse (NIDA) in the Alcohol, Drug Abuse, and Mental Health Administration will expand its activities aimed primarily at the IV drug abusers from $31 million in 1987 to $76 million in 1988. NIDA will support community-based outreach demonstration projects to prevent the spread of AIDS among the drug abusing populations.

In the area of health care delivery, HRSA has awarded grants for AIDS Service Demonstration Projects in 13 metropolitan areas which fall within the Nation's 25 areas with the highest incidence of AIDS. These projects will identify ways to reduce health care costs for both minimally ill AIDS patients and terminally ill AIDS patients by providing alternatives to inpatient hospital care such as hospices.

In summary Mr. Chairman, the FY 1989 request of $1.3 billion includes an increase of $349 million or 37 percent over the FY 1988 level of $951 million. AIDS related FTEs will also increase in FY 1989. Additional lab space is also coming on line or is planned for construction. Increases are proposed in all aspects of the PHS-supported AIDS research and prevention activities. Emphasis will be placed on developing and applying various vaccine and therapeutic intervention strategies; expanding basic research to further understand the disease and how it manifests itself; conducting intensive epidemiological studies to trace the incidence of AIDS and modes of transmission; expanding seroprevalence efforts begun in 1988 to determine more accurately the current nationwide prevalence of HIV infection, and to predict better its future occurrence; providing accurate and up-to-date information on AIDS to the general public, school and college-aged populations, health care workers, and high risk populations (including minorities and IV drug abusers) to encourage individuals to minimize behavior that risks spreading or contracting the disease; and initiating a new $40 million treatment program for IV drug abusers.

## PUBLIC HEALTH SERVICE MANAGEMENT

The FY 1989 budget request of $194 million for the PHS Management appropriation is approximately the same as the FY 1988 comparable level of funding.

The FY 1989 budget request includes $18.5 million of budget authority for the National Center for Health Services Research and Health Care Technology Assessment. The Center is the primary source of Federal support for research on problems related to the quality and delivery of health services. The budget request will support the Center's on-going extramural research activities and will provide continuation support for the National Medical Expenditure Survey (NMES). The project is on schedule and by the summer of 1988, the household and institutional components of the survey will be completed. Surveys of employers, providers and insurers will begin in September 1988 and will be completed by April 1989. With the addition of these components, NMES will become one of the most important databases available for Federal health policy analysis.

The budget request includes $9.6 million for the Adolescent Family Life Program to continue that activity at the FY 1988 level. The program will support demonstration and research projects and will continue to promote adoption as a positive alternative to early parenting.

In FY 1989 $140 million is being requested for grants and personnel costs for a Family Planning Block Grant program to supersede the Family Planning categorical program which has previously been appropriated to the Health Resources and Services Administration. The proposed block grant will support direct awards to the states and territories and will provide the states both the resources and control over the resources to deliver voluntary family planning services that are responsive to and in accordance with state law and other state administered health care programs.

The budget request of $3 million for the Disease Prevention and Health Promotion activity will enable the program to continue to focus its efforts on the National Health Objectives for the Year 1990 and the development of the National Health Objectives for the Year 2000. The budget request of $1.5 million for the Physical Fitness and Sports activity provides support for the continued development and promotion of exercise and physical fitness programs in cooperation with the public and private sector.

The budget includes a request of $2.9 million for the Office of Minority Health to continue its role in coordinating and monitoring the implementation of the recommendation contained in the Secretary's Task Force on Black and Minority Health. The efforts are aimed at reducing the disparity in the health status between minority and non-minority populations and focuses on modifying those behavior patterns or preventable conditions which contribute to excess mortality among minorities. In FY 1989, the Office of Minority Health will continue the risk reduction coalition grant program and manage a Department-wide coordination and planning process to develop goals and objectives in minority health.

For the management and direction of the Public Health Service, we are requesting $18.7 million.

## RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

The Retirement Pay and Medical Benefits for Commissioned Officers appropriation provides retirement payments to Public Health Service Commissioned Officers, payments to survivors of officers who elected to receive a reduced annuity, and the costs of medical care of active duty and retired officers, their dependents and survivors.

The FY 1989 budget request for the entitlement program is $107.7 million, an increase of $17.8 million over the FY 1988 level and includes a reserve fund of $5 million and $6.7 million for military service credits. The reserve fund will be available only to the extent necessary for unanticipated costs in the budget estimates. The amount for military service credits is being requested to reimburse the Social Security Administration to cover the value of non-wage income such as food, shelter, and medical care.

Mr. Chairman, I will be pleased to answer any questions you may have.

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## BIOGRAPHY OF DR. ROBERT E. WINDOM

Robert E. Windom, M.D., was sworn in June 23, 1986, as assistant secretary for health, Department of Health and Human Services. Dr. Windom was nominated by President Reagan May 8, 1986, and confirmed by the Senate June 19, 1986.

Before joining HHS, Dr. Windom was a practicing physician specializing in internal medicine, in Sarasota, Fla. He has been clinical professor of internal medicine at the University of South Florida School of Medicine and clinical associate professor of internal medicine at the University of Miami School of Medicine.

As assistant secretary for health, Dr. Windom directs the activities of the Public Health Service, which includes the Health Resources and Services Administration; the Alcohol, Drug Abuse and Mental Health Administration; the Centers for Disease Control; the Food and Drug Administration; the National Institutes of Health; and the Agency for Toxic Substances and Disease Registry.

Dr. Windom provides policy guidance for other HHS programs including the Health Care Financing Administration, which administers Medicare and Medicaid. He also maintains relationships with other government and private agencies concerned with health: He advises and assists the Secretary on health policy and on all health-related activities.

Dr. Windom was born July 14, 1930, in Columbus, Ohio. He received his B.S. and M.D. degrees from Duke University in 1952 and 1956, respectively. He served his internship and residency in internal medicine at Parkland Memorial Hospital in Dallas, Texas.

He is a past president of the Florida Medical Association, the Florida Heart Association, the Florida Medical Political Action Committee and the Sarasota County Chamber of Commerce. He served as a delegate to the American Medical Association, as a member of the National Board of the American Heart Association and as a member of the Advisory Council to the National Institute on Aging. Dr. Windom has been chosen as a distinguished alumnus of the Duke University School of Medicine and he won the Health Communicator of the Year Award from the Florida Hospital Association for his 10 years of producing and hosting regular television programs on health topics.

He has written numerous articles on medical subjects and has lectured frequently on various topics related to health. He is a Fellow of both the American College of Physicians and the American College of Cardiology. He is certified by the American Board of Internal Medicine and has been an active member of the American Society of Internal Medicine.

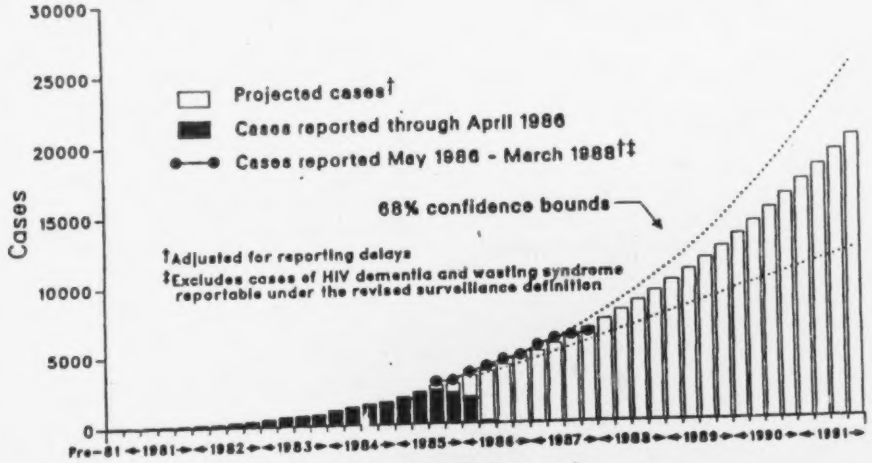
Dr. Windom and his wife, the former Lelia Ann Harmon, have three sons: Robert Jr., Ross and Hugh.

## PUBLIC HEALTH SERVICE

### Acquired Immune Deficiency Syndrome (dollars in millions)

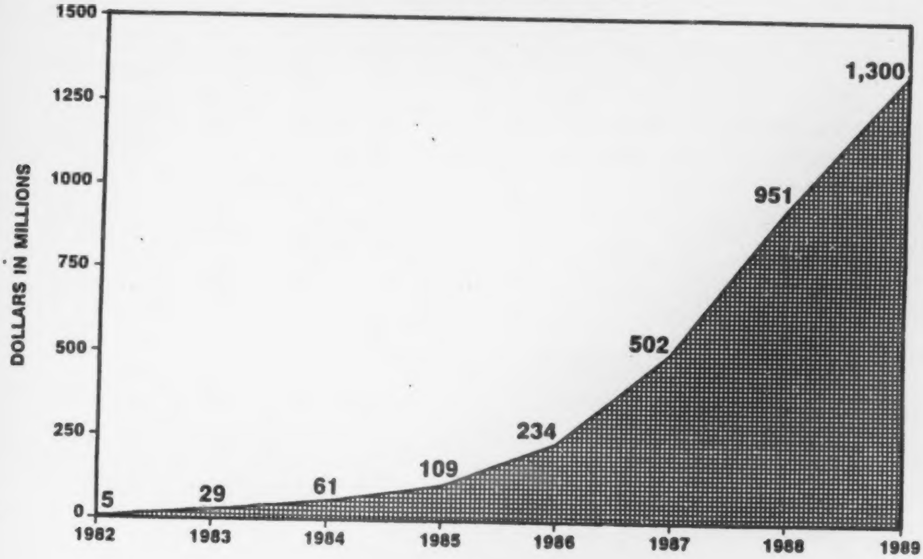
| | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| Dollars | $ 502 | $ 951 | $1,300 | +$349 (+37%) |
| FTEs | 794 | 1,145 | 1,368 | + 223 (+19%) |

Incidence of AIDS in the United States, by Quarter-Year of Diagnosis Projected from Cases Reported as of April 30, 1986 and Shown with Cases Reported as of March 31, 1988



## AIDS

### Growth in PHS Spending



## PUBLIC HEALTH SERVICE
### Acquired Immune Deficiency Syndrome
### (Dollars in Millions)

| | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| Research | $327 | $636 | $860 | $+224 |
| Prevention | 175 | 315 | 440 | +125 |
| (INFORMATION & EDUCATION) | (132) | (296) | (374) | (+ 77) |
| **PHS TOTALS** | **$502** | **$951** | **$1,300** | **$+349** |

## PUBLIC HEALTH SERVICE
## AIDS Research
## (dollars in millions)

| | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| Disease Studies and Surveillance | $154 | $276 | $386 | +$109 |
| Epidemiological (non-add) | (59) | (95) | (133) | (+38) |
| Surveillance (non-add) | (13) | (64) | (96) | (+32) |
| Therapeutics | 129 | 176 | 243 | +68 |
| Vaccines | 33 | 62 | 93 | +30 |
| Multidisciplinary | — | 92 | 96 | +4 |
| Health Service Activities | 11 | 29 | 28 | −1 |
| Contingency* | — | — | 15 | +15 |
| Total, Research | $327 | $636 | $860 | +$224 |

*Contingency may be used for research or prevention.

## PUBLIC HEALTH SERVICE
## AIDS Prevention
## (dollars in millions)

| | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| Information and Education: | | | | |
| General public | $ 29 | $ 50 | $ 51 | +$ 1 |
| School and college aged | 11 | 30 | 36 | + 7 |
| High risk or infected persons | 82 | 190 | 242 | + 52 |
| Testing, counseling referral (non-add) | (26) | (72) | (104) | (+31) |
| Health care workers | 11 | 27 | 44 | + 17 |
| Subtotal, Information and Education | 133 | 296 | 374 | + 77 |
| Prevention—other | 43 | 19 | 67 | + 48 |
| Total, Prevention | $175 | $315 | $440 | +$125 |

# PUBLIC HEALTH SERVICE
## Pediatric AIDS

**Problem:**

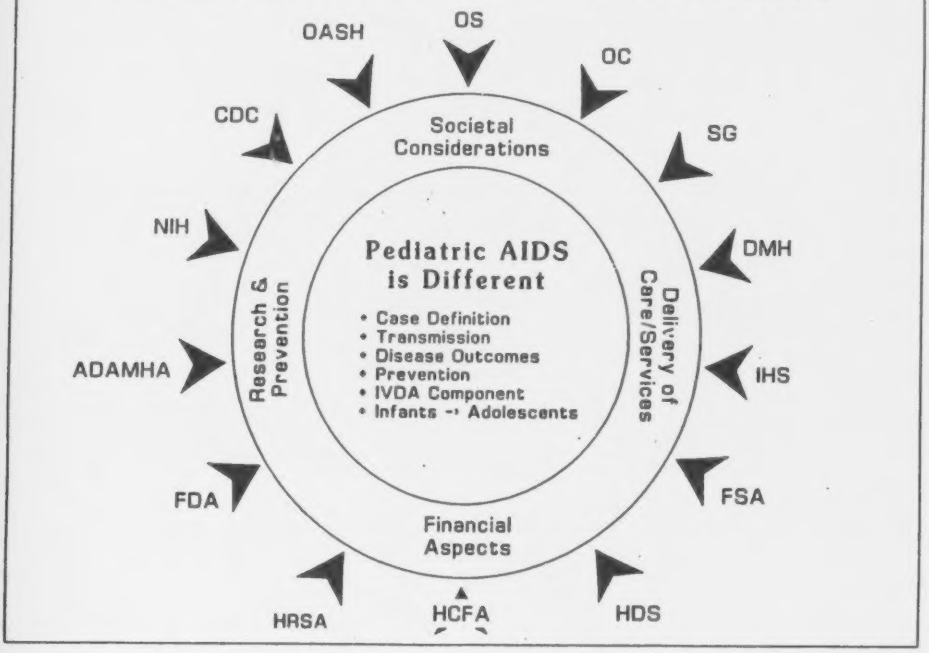
- 932 cases already identified as of 4/11/88
- Expected to grow significantly
- Significant health care costs

**PHS Response:**

Secretary's Pediatric AIDS Initiative

- Established Pediatric AIDS Task Force
- Provide a focus within the Department
- Eliminate unnecessary barriers
- Coordinate research and demonstration agenda
- Provide technical assistance
- Identify prevention activities

### SECRETARY'S PEDIATRIC HIV INITIATIVE


OS
OASH
OC
CDC
SG
NIH
DMH
ADAMHA
IHS
FDA
FSA
HRSA
HCFA
HDS
Societal Considerations
Research & Prevention
Delivery of Care/Services
Financial Aspects
Pediatric AIDS is Different
• Case Definition
• Transmission
• Disease Outcomes
• Prevention
• IVDA Component
• Infants → Adolescents

# PHS AIDS FUNDING
## (Dollars in Millions)

| Agency: | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| FDA | $16 | $25 | $65 | $+ 40 |
| HRSA | 12 | 37 | 40 | + 3 |
| CDC | 136 | 305 | 401 | + 96 |
| NIH | 261 | 468 | 588 | +120 |
| ADAMHA | 47 | 112 | 178 | + 66 |
| OASH | 30 | 4 | 13 | + 9 |
| CONTINGENCY | — | — | 15 | + 15 |
| TOTAL—AIDS | $502 | $951 | $1,300 | $+349 |

# PUBLIC HEALTH SERVICE
## Acquired Immune Deficiency Syndrome
## FTEs

| | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| FDA | 90 | 127 | 254 | +127 |
| HRSA | 7 | 25 | 25 | — |
| IHS | — | — | — | — |
| CDC | 271 | 416 | 432 | + 16 |
| NIH | 399 | 510 | 580 | + 70 |
| ADAMHA | 20 | 47 | 57 | + 10 |
| OASH | 7 | 20 | 20 | — |
| Total, PHS | 794 | 1,145 | 1,368 | +223 |

## Acquired Immune Deficiency Syndrome
## Total Federal Government Spending
## (dollars in millions)

| | 1982 | 1983 | 1984 | 1985 | 1986 | 1987 | 1988 | 1989 |
|---|---|---|---|---|---|---|---|---|
| Public Health Service . | $6 | $29 | $61 | $109 | $234 | $502 | $951 | $1,300 |
| Medicaid (Federal share) | — | — | — | — | 130 | 210 | 375 | 600 |
| Medicare . . . . . . . . . . . | — | — | — | — | — | 10 | 15 | 25 |
| Social Security Admin . | — | — | — | — | — | 41 | 71 | 111 |
| Veterans Administration | 2 | 5 | 6 | 12 | 24 | 30 | 52 | 66 |
| Defense Department . . | — | — | — | — | 79 | 74 | 52 | 52 |
| Justice/Bureau of Prisons . . . . . . . . . . . | — | — | — | — | 1 | 3 | 6 | 6 |
| State Department . . . . . | — | — | — | — | — | 1 | 2 | 2 |
| Labor Department . . . . | — | — | — | — | — | 1 | 1 | 1 |
| Agency for International Dev. . . . | — | — | — | — | 2 | 17 | 30 | 30 |
| Total, Federal Govt. . . . | $8 | $34 | $67 | $121 | $470 | $889 | $1,555 | $2,193 |

PUBLIC HEALTH SERVICE

AIDS Cases and Known Deaths

| | Cases Reported to CDC | | | Known Deaths | | |
|---|---|---|---|---|---|---|
| | Adult | Pediatric | Total | Adult | Pediatric | Total |
| 1981. . . . . . | 199 | 0 | 199 | 113 | 8 | 121 |
| 1982. . . . . . | 691 | 13 | 704 | 408 | 11 | 419 |
| 1983. . . . . . | 2,067 | 34 | 2,101 | 1,353 | 29 | 1,382 |
| 1984. . . . . . | 4,503 | 49 | 4,552 | 3,105 | 44 | 3,149 |
| 1985. . . . . . | 8,233 | 131 | 8,364 | 5,834 | 100 | 5,934 |
| 1986. . . . . . | 13,083 | 198 | 13,281 | 9,366 | 130 | 9,496 |
| 1987. . . . . . | 20,866 | 332 | 21,198 | 11,061 | 204 | 11,265 |
| Thru 4/18/88. . | 8,915 | 177 | 9,092 | 1,388 | 15 | 1,403 |
| CUMULATIVE. . . | 58,557 | 934 | 59,491 | 32,736* | 544* | 33,280 |

* Includes 108 adult and 3 pediatric cases whose year of death is unknown or is prior to 1981.

### PUBLIC HEALTH SERVICE

### Distribution of New AIDS Cases Reported to CDC

| | 1987 |
|---|---|
| Homosexual or Bisexual Men | 63.9% |
| Intravenous (IV) Drug Abusers | 17.1% |
| Homosexual Men & IV Drug Abusers | 7.0% |
| Persons with Hemophilia or Coagulation Disorder | 1.1% |
| Heterosexual Partners of High Risk Persons | 4.0% |
| Recipients of Blood Transfusions, Components, or Products | 2.9% |
| Undertermined Origin of AIDS Infection | 4.0% |
| Total | 100.0% |

## PUBLIC HEALTH SERVICE
## AIDS Achievements

| | |
|---|---|
| 1981 | AIDS recognized as new disease. |
| 1982 | Public information and education program begun. |
| 1983 | PHS Executive Task Force on AIDS established. |
| | National AIDS hotline initiated. |
| 1984 | AIDS virus identified. |
| | AIDS blood test developed. |
| 1985 | AIDS blood test licensed. |
| | Screening of nation's blood supply begun. |
| | Funded alternate test sites. |
| 1986 | Proved efficacy and safety of AZT. |
| | Initiated animal testing of vaccines. |
| | Coolfont and Surgeon General's reports. |
| | Federal Coordinating Committee established. |
| | Expanded Health Education/Risk Reducation programs. |
| 1987 | Approved new drug application for AZT. |
| | Implemented new comprehensive information and education plan. |
| | Accelerated drug discovery and clinical trial activities. |
| | Licensed Western blot test kit. |
| | Initiated human testing of vaccines. |
| | Implemented IV drug abusers initiative. |
| | Distributed over 13 million copies of Surgeon General's report. |
| 1988 | Initiated family of seroprevalence surveys. |
| | Prepared for distribution a mailer to every household by end of June. |
| | Established Secretary's Pediatric AIDS Initiative. |

## PUBLIC HEALTH SERVICE
## Pediatric AIDS
## (dollars in millions)

| | 1987 | 1988 | 1989 | Change 88/89 |
|---|---|---|---|---|
| HRSA | — | $ 5 | $ 5 | — |
| CDC | $ 4 | 19 | 19 | — |
| NIH | 11 | 29 | 45 | +$ 16 |
| ADAMHA | 4 | 5 | 5 | +1 |
| Total, PHS | $20 | $58 | $75 | +$17 |

### INTRODUCTION OF ASSOCIATES

Dr. WINDOM. I would like to introduce the people at the table with me. To my right is Mr. Forbush, Dr. Fauci, and Mr. Williams, and Mr. Little here to my left, and Dr. Fischinger and Dr. Mason. We have others to answer questions, if it is required.

First of all, we appreciate the opportunity to appear today to discuss our fiscal year 1989 budget request for the Office of the Assistant Secretary for Health. This includes the AIDS research and education appropriation request of $1.3 billion, the Public Health Service management appropriation request of $194 million, and the retirement pay and medical benefits for commissioned officers appropriation request of $108 million.

### AIDS RESEARCH AND EDUCATION

Talking first about AIDS research and education, as you well know, Mr. Chairman, AIDS is our No. 1 public health priority.

The request of $1.3 billion includes a 37-percent increase over fiscal year 1988, and represents our best estimate of what is needed to maximize our battle against this disease.

The budget requests for AIDS have been consolidated in a single appropriation in fiscal year 1989 in order to improve coordination, flexibility, and visibility for the high level of resources being devoted to this top public health priority.

Consolidating the AIDS funds will build upon the research and prevention flexibility available in fiscal year 1988 to respond to scientific breakthroughs and unexpected crises as they occur. However, operational responsibility will continue to reside in the individual PHS agencies involved.

In 1987, over 21,000 new cases of AIDS were reported, a 60-percent increase over 1986. In total, over 59,000 AIDS cases and more than 33,000 AIDS-related deaths in the United States have been reported to the Centers for Disease Control since June 1981. There has been no documented case of recovery from fully developed AIDS.

Mr. Chairman, in response to this menacing problem, the priorities of the Public Health Service have been very clear and we have made extraordinary progress against AIDS in a relatively short period of time, more than against any other complex new disease in the history of medicine.

As a result of this progress, today we have some promising programs underway. In the drug development area, under the AIDS Clinical Trials Groups Program, NIH has established 18 drug treatment evaluation units and 17 clinical trial units. Over 25 active research protocols are being conducted with the enrollment of over 3,200 patients. More than eight new potential antiviral drugs entered clinical trials in the past year.

In the vaccine area, clinical trials of two experimental AIDS vaccines are currently in progress in the United States.

In the prevention area, several PHS agencies have been initiating new information and education programs, and expanding existing programs to prevent the spread of the disease.

The Centers for Disease Control has directed a national public information campaign for the Public Health Service, expanded HIV counseling and testing to health care settings serving high-risk individuals including IV drug abusers, initiated new programs for school- and college-aged populations and minorities, and planned for an every-household mailer to be distributed in June of this year.

CDC has also begun a comprehensive program of HIV seroprevalence surveys that will provide important information on the spread of HIV infection in the general population. NIDA has initiated major prevention programs aimed at the IV drug abuser.

Mr. Chairman, much work remains to be done. Therefore, the fiscal year 1989 request of $1.3 billion includes an increase of $349 million over the fiscal year 1988 level of $951 million. Increases are proposed in all aspects of PHS-supported AIDS research and prevention activities.

Emphasis will be placed on developing and applying various vaccine and therapeutic intervention strategies; expanding basic research to further understand the disease and how it manifests itself; conducting intensive epidemiological studies to trace the incidence of AIDS and modes of transmission; expanding seroprevalence efforts begun in fiscal year 1988 to determine more accurately the current nationwide prevalence of HIV infection and to predict better its future occurrence; providing accurate and up-to-date information on AIDS to the general public, school- and college-aged populations, health care workers, and high-risk populations, including minorities and IV drug abusers, in order to encourage individuals to minimize behavior that risks spreading or contracting the disease; and initiating a new $40 million treatment program for IV drug abusers.

## PUBLIC HEALTH SERVICE MANAGEMENT

Now for Public Health Service management. The fiscal year 1989 budget request of $194 million for the PHS management appropriation will continue support for several small but important PHS activities at approximately the same as the fiscal year 1988 comparable level of funding.

For the National Center for Health Services Research, $18.5 million is requested to support the Center's ongoing extramural research activities, and to provide continuation support for the national medical expenditure survey.

The request also includes $140 million for a Family Planning Block Grant Program to supersede the Family Planning Categorical Program which has previously been appropriated to the Health Resources and Services Administration.

## RETIREMENT PAY AND MEDICAL BENEFITS FOR COMMISSIONED OFFICERS

For retirement pay and medical benefits for commissioned officers, the fiscal year 1989 budget request is $107.7 million, an increase of $17.8 million over the fiscal year 1988 level.

Mr. Chairman, that concludes my summary remarks, and as you mentioned my full statement will be submitted for the record.

## AIDS OVERVIEW

Dr. WINDOM. I have some charts to show you. The first gives a breakdown of the total AIDS budget for 1987, 1988, and 1989. It shows the total increase from 1988 to 1989 of 37 percent in dollars and a 19-percent increase in our FTE's.

This next chart shows a continuation of the projection of incidence of AIDS in the United States that we made 2 years ago as a prediction of new cases reported over the years up to 1991.

The green line shows that we are continuing on that projection, and nothing has occurred to change those estimates since they were first made.

Senator CHILES. What is the difference between your dotted line——

Dr. WINDOM. The dotted line gives you the range that, as you set projections, you can have a confidence boundary on one side or the other, and the middle, of course, would be the average. We are going right on that middle track.

Senator CHILES. You are following the average track.

Dr. WINDOM. Right. This next chart is a very dramatic presentation, I feel, that shows the growth in PHS spending on AIDS from 1982 at just $5 million to the 1989 request of $1.3 billion.

Never before has such an escalation occurred in the history of the Public Health Service. The total expenditures of Federal dollars on all sorts of AIDS programs is projected at $2.2 billion for fiscal year 1989.

This chart breaks down very nicely the amount of money for AIDS research and prevention, and showing significant increases in both of those over 1988. About two-thirds of our AIDS budget will go into the research area, and one-third into prevention activities, primarily information and education programs.

The next one breaks down the AIDS research dollars throughout the Public Health Service, as far as the major categories in research, the total amount being a $224 million increase. You can see how we have broken that into disease studies and surveillance, vaccines and therapeutics, which are particularly important to find a cure for the disease, and then the other activities along with a contingency fund of $15 million requested for this year.

This chart breaks down the AIDS prevention activities, and shows a $125 million total increase. Again, this is one-third of the overall budget. It is broken down into the targeted populations which all show significant increases. You can see where it says, "prevention—other," the last line, $40 million of that is specifically designated for new drug intervention therapy programs in different parts of the country.

This chart breaks down our pediatric AIDS initiative. We are realizing more and more that this is a very significant problem. We have over 932 cases reported as of just the last week. We expect this will go up to maybe 3,000 cases in the year 1991.

We have developed a very specific pediatric AIDS initiative including a pediatrics AIDS task force under the direction of Dr. Novella, who is the Deputy Director of the National Institute of Child Health. Her committee members are working very diligently in this area.

Senator WEICKER. How many cases did you say this was to grow to?

Dr. WINDOM. About 3,000. We are at more than 900 now.

Senator CHILES. How many cases do you think we actually have now that are not reported? I mean, we have got a lot more cases than we have reported.

Dr. WINDOM. There may be some, but it is easier to detect pediatric AIDS cases because of the birth in the hospital setting, whereas the other cases are diagnosed outside the hospital setting and it is more difficult.

By the year 1991 there may be 10,000 to 20,000 children infected, probably 3,000 with the disease.

Senator WEICKER. What do you consider pediatrics?

Dr. WINDOM. This is from the date of birth up until age 13. Most of the cases reported now are within the first 3 years of life. We have some others up to age 13.

This next chart gives you a general idea of how extensively the pediatric AIDS issue involves all the agencies within PHS, and even other operating divisions within the Department of HHS.

The disease itself is different in pediatric cases because of how it manifests itself compared to adult cases. The transmission is, of course, from the mother, and the outcome is very progressive in the course of the clinical events, and the relationship primarily to the IV drug abuser situation.

This chart shows the funding levels for AIDS broken down into the agencies within the Public Health Service. On the right, you can see the increase of $349 million over the 1988 dollar level. At the bottom, the total request for 1989 is $1.3 billion. It shows you that the AIDS budgets for all of our agencies are increasing, with the research at the NIH being the largest amount, but the NIH basic non-AIDS budget is also the largest.

This final chart shows a breakdown for the FTE's that are within the Public Health Service agencies, and, of course, the need to have more people as we continue to carry out the demands of this disease.

That concludes my formal presentation. We will be happy to answer any questions.

Senator CHILES. Senator Weicker, do you have an opening statement?

Senator WEICKER. No.

Senator CHILES. Senator Inouye, we are delighted to have you here. Do you have questions?

### PACIFIC BASIN INITIATIVE

Senator INOUYE. I thank you very much. Mr. Chairman, I wanted to come by and pay my respects, and commend Dr. Windom for looking into an area that has been too often forgotten, and that is the Pacific Basin.

They are not in my jurisdiction or in my constituency. But it is an important area to the United States, geopolitically and strategically. And this is the area that has most of the exotic diseases, the high incidence of such. And Dr. Windom's recognition of this is duly noted in that area. And on behalf of those people, I thank you, sir.

Dr. WINDOM. Thank you.

### IHS PROFESSIONALS SALARIES

Senator INOUYE. I have questions, Mr. Chairman, I would like to submit, if I may, and close by asking one question.

Dr. Windom, I am chairman of the Select Committee on Indian Affairs, and as such we work very closely with the Indian Health Service.

And during one of our hearings I noted that the professionals in Indian Health Service, the doctors, the nurses, the paramedics, and such, had noticeably lower wages than, say, VA doctors and nurses and paramedics. Why is that?

Dr. WINDOM. Well, historically, the funding and the salary ranges have been lower in those areas. As you know, many of them start out in the National Health Service Corps paying back obligations and, therefore, the salary level was lower.

But we hope we can get that raised as we progress along each year, and bring it up to a level that is comparable. But for now, it remains below.

Senator INOUYE. Obviously, retention would be almost impossible. The working conditions are not the best.

Dr. WINDOM. Right.

Senator INOUYE. They are out in the no-man's land, out in the deserts. And I would hope that your agency can look into this so that we can retain some of them, and encourage others to volunteer.

Dr. WINDOM. Many of them are there because of their determination and dedication to the cause, and we certainly admire that. But they need to be paid properly too.

Senator INOUYE. I thank you very much.

### AIDS INFECTION IN THE HETEROSEXUAL POPULATION

Senator CHILES. Thank you, sir. Dr. Windom, the charts you showed us on the projected incidence for AIDS seem to show a leveling off.

We know, for example, that the statistics for HIV infection among military applicants, blood donors, and the job corps has remained constant, and the rate among heterosexuals has remained stable at 4 percent.

Surgeon General Koop was recently quoted as saying, do not sit trembling in fear that tomorrow there is going to be an explosion of AIDS in the heterosexual population the way it was in the homosexual population in 1981 and 1982, because it does not seem to be happening.

Is the AIDS epidemic spread into the general population coming under control? Is it constant? I see, for example, you still estimate that there are 1.5 million people, HIV-infected people, in the United States, and that that figure has not gone up.

Dr. WINDOM. Yes. sir; we feel that those projections that were made in June 1986 remain the same.

We are not seeing a rampant increase of heterosexual AIDS cases, but we are not seeing a rapid decline either.

It is going on at a steady pace. We are doing further evaluation with the nationwide surveillance study that is starting this year. The preliminary part of that, hopefully, will give us more exact data to show the true prevalence of this disease within the Nation.

At the present time, all the sources we have show that the 1.5 million estimate for the number of people infected with AIDS is still the rough figure that is holding true. The military incidence is leveling off also due to the fact that many individuals who would have applied for recruitment realized that they were going to be tested, so if they are at high risk they are not applying.

Most of those who do apply and are infected are those who do not realize, who are high risk, and happen to be positive as a result of some association. It is the same for those going for blood donations. If they are high risk, they are not going. So we expect that to level off also.

But the number of reported cases is increasing. As you mentioned, we are sure that there are other cases out there that are not reported even though we have the best reporting mechanism in the world.

## HIV MUTATION

Senator CHILES. Dr. Fauci, I want to take comfort in the fact that these figures seem to be that way, and my understanding is that we still do not have any incidences of cases from casual contact, as people use that term.

But I am concerned a little bit knowing we are dealing with a virus, and when I look at what has happened to influenza and flu and the different mutations and strains of that virus, some people tell me you cannot take too much comfort in what has happened today because this virus is capable of mutation and changes.

What can you tell me about that as a layperson? I do not understand that really, but I want to know, you know, how much comfort can we take, and what is our—is there any way of determining what kind of probabilities of mutation there is in this, that casual contact could become a way of infecting?

Dr. FAUCI. Virtually all viruses mutate to a greater or lesser degree. A virus which mutates and is common in the environment is influenza. It changes so that from one year to another your protection——

Senator CHILES. When we say mutate, what——

Dr. FAUCI. For example, a virus has a structural component around it like an outer coating. If I am infected with this virus my body will make a response against the different components of the outer coating.

Next year, if I get infected with that same influenza virus, my body's immune system will immediately recognize those same structural components and be able to suppress it before I get sick again. That is why I would be protected.

However, if an influenza virus comes along 2 or 3 years from now that has made a significant enough change in its structural components, my body's defenses will not recognize that as readily and I might get sick before I would be able to suppress it.

This structural change component does not change the way influenza is spread, by sneezing or by coughing. So if you extrapolate that to the AIDS virus, the AIDS virus has an outer coating which we call the envelope. This envelope is the area where the greatest change from one isolate to another occurs.

And, in fact, there is a great deal of what we call heterogeneity and variability from isolates that you might find in Florida versus California versus New York, and certainly more than you would see, for example, from an isolate that is in central Africa.

Senator CHILES. What is an isolate?

Dr. FAUCI. If you examine a virus at the molecular level from someone who is in San Francisco, someone in New York, and from someone from Kinshasa in Zaire, the structural component of the virus will all be different.

With the AIDS virus, there may also be some significant differences in the structural component of that outer coating which we call the envelope.

Even though there is a great deal of variability, the probability of a structural component change being so great that it would actually change the way a virus is transmitted, is such an incredibly small possibility that it should not even be considered.

For example, the chances of a virus mutating to the point of becoming less virulent or not infecting man is infinitely greater than the chances of a virus mutating to a point where it begins being spread by the respiratory route.

In biology there is always a finite possibility. But because of what we know about how viruses mutate, there is virtually no chance a mutation would occur that would change the way it is spread.

Senator CHILES. You do not see that as a problem?

Dr. FAUCI. No; I do not.

### PROGRESS ON VACCINE DEVELOPMENT

Senator CHILES. Last year we discussed a poll of 227 scientists, 46 percent of which felt that we would have a vaccine by the year 2000.

I know you currently have clinical trials underway to test two vaccines in a group of 81 people. What progress is being made to find an effective vaccine? And has anything changed in our timeframe at all?

Dr. FAUCI. As I said to this committee last year and have discussed with individual Members at various times, we still feel that if we are fortunate enough to develop a vaccine, it will not be until the mid-1990's until we have one available for widespread use.

Let me very briefly tell you what is going on. There are now two Government-sponsored vaccine clinical trials using an AIDS recombinant DNA product.

A highly purified protein of the virus called GP–160, which is part of that envelope that I was just telling you about.

One of the trials is a phase 1 trial, which will determine if a particular product is safe enough to use in a phase 2 or phase 3 trial.

In addition to safety, we are asking if it elicits an antibody response. This trial is taking place on the NIH Bethesda campus. Eighty-one people are in this trial and it is going along well. It is, by necessity, a small trial, because when you are trying to establish safety you always go with very small numbers.

We have accrued about two-thirds of the patients targeted to be involved. No toxic side effects have been noted as yet and there are no scientific results vis-a-vis responses.

The same protein—GP–160— is being tested at six NIH-sponsored vaccine evaluation units throughout the country sponsored by the NIAID extramural AIDS program which will have 72 people enrolled.

The trial at the NIH involves male homosexuals; the trial in the extramural program involves men, women, homosexuals, and heterosexuals; and, there is another trial that is not Government sponsored.

Senator CHILES. How long will those trials take?

Dr. FAUCI. Phase 1 trials usually take from 6 months to 1 year. If it is successful and there are no toxic side effects, you move to phase 2, which involves a larger number of people to determine the proper dosage and in addition to more information on safety.

A phase 2 trial would run anywhere from 1 year, 1½ years, to 2 years. If that is successful, then and only then do you go on to a phase 3 trial, which involves much larger numbers of individuals, to establish whether or not it is an effective vaccine.

A phase 3 vaccine trial, that will not be completed until well into the 1990's, even if we are successful in getting to that point.

Senator CHILES. Has anything changed in our strategy? Or are we still looking for a cure? Or are we trying to——

Dr. FAUCI. Actually we are doing two things. We are looking for a cure through the Drug Development and Clinical Trial Program, and we are looking for a vaccine through our Vaccine Development and Evaluation Program.

At the same time, we are intensifying our educational efforts in order to have a public health measure to control the spread of the virus.

### AIDS HOUSEHOLD MAILER

Senator CHILES. Dr. Mason, as you know, this committee has felt very strongly about the need to get out the facts on AIDS to every household in America.

We put money in the 1987 supplemental. We had to restate our intentions more clearly to the White House in last year's bill. What is the status of the AIDS household mailer? And will the increase in the postal rates have any effect on this program?

Dr. MASON. We are happy to report to you that a great deal of progress is being made, and we will comply with Congress' statement in our appropriations act that we should have a mailout to every home in the United States by June 30, 1988.

Everything is on target. Actually, right now at a large printing press here in the United States, they are currently printing 6 million pounds of mailouts. That is over 107 million copies, which will be distributed by the U.S. Postal Service.

The postal rate increase has resulted in a higher cost than we estimated last year.

Everything is moving along on schedule, and we think we will have a product to every household in the Nation that you will be proud of.

Senator CHILES. Doctor, I think that Senator Weicker and I would both like to see a copy of that.

My understanding is in Great Britain, when they sent out their mailer, they had an awful lot of inquiries, telephone and others, people seeking additional information. What have we set up——

Dr. MASON. We have been in communication with our British counterparts, and we are clearly aware of some of the problems that can be created by a mailer to each household.

As a result of that, we have met with AT&T, and they are working with us. From May 23 and throughout the period of distribution, and then for a few weeks afterwards, we will have a flexible group of more than 1,000 operators who will be on standby to respond to calls that may come in from people who received the mailout.

We are also working with States and communities, because the AT&T operators will largely be referring people to State health departments and to State and local hotlines. So we have, I think, a very intricate but very workable system to handle calls.

We are increasing the capacity of the National AIDS Clearinghouse, so that people who call in for additional copies will get a 48-hour turnaround time. We have done everything we can to anticipate any problems that may come up.

We are also sending out copies of the brochure a few days before it gets to each household to more than 1 million health care workers, physicians, dentists, nurses, and others, so that they will have a preview ahead of all of the households, because the mailout encourages people to see your own private physician, your health clinic, your hospital.

And we hope to defer some of the calls to the national hotline by encouraging people to go to local providers and then bring the local providers up to speed so that they will be ready to provide answers to any questions that may come as a result of the mailout.

### ADEQUACY OF AIDS FTE'S AND FACILITIES

Senator CHILES. Dr. Windom, AIDS funding has increased twelvefold since 1985. But the personnel levels have only increased threefold.

We hear complaints from agencies regarding the need for more personnel, and we also hear requests for more AIDS-related facilities.

In fact, we have learned that in the professional judgment requirements the Public Health Service has estimated an additional need for 506 full-time equivalent positions. And at least $48 million in laboratory and office space for AIDS-related activity.

Those requests were in addition to the 1989 budget request. We know you are here to defend the President's budget, but what is your view? Do you need to spend more money for FTE's and building space?

Dr. WINDOM. Yes, sir; we have proposed increases, which are broken down on the chart between our agencies. We also believe that the demand has been met quite well with the increased dollars, with the system as it is.

We have requested FTE's that we feel will be necessary to make that complement adequate to carry out our AIDS responsibilities.

As far as structure is concerned, we feel that there may be a need for more to adequately have a facility that would house the people better, and more efficiently too. That is something we are looking into.

### OMB INCREASES TO AIDS BUDGET REQUEST

Senator CHILES. Well, we know that OMB very uncharacteristically increased your AIDS budget from $1.145 billion to $1.3 billion. Those adjustments were made in January.

Since then, and also since last September when you made a request, what changed to suggest the need for more funding there?

Dr. WINDOM. OMB added $155 million to our budget request for AIDS to continue the 1988 congressional increases which were not considered when we sent our budget request to OMB, and to add additional moneys for the seroprevalence study that is underway which is a significant increase. The seroprevalence study request was developed after we sent our initial budget request to OMB.

Senator CHILES. Since then, have things changed to suggest the need for more money?

Dr. WINDOM. At this time we believe the current request of $1.3 billion will be adequate.

Senator CHILES. Senator Weicker?

## RESTRICTIVE APPROPRIATIONS BILL LANGUAGE

Senator WEICKER. Thank you very much, Mr. Chairman. I first of all want to make sure that those questions which I do not get to ask this morning will be submitted for response to the record.

Senator CHILES. They will be, and I have some questions I am sure I will submit, and probably the other Members.

Senator WEICKER. Dr. Mason, last year the Senate tacked on an amendment to the appropriations that related to the CDC's communications with the homosexual community, in terms of the education process, or the information process, however you want to phrase it.

How restrictive has the effect of that amendment been on the performance of that aspect of your agency's work?

Dr. MASON. You are referring to the amendment that not only involved homosexuality but drug abuse as well.

In terms of our in-house programs, it took about an additional month to process our request for proposals from the States, because we had to revise the materials that we were preparing to send out, so the States would be able to respond for their grants. Once we were over that, we moved ahead vigorously.

I think our main problem is that the States and the communities are not quite sure how to interpret the language. We got some clarification when the House and Senate met in conference on the final appropriations language.

But I think we are going to see a mixed reaction with regard to this, because some communities will interpret it very conservatively, and some communities will interpret it very liberally.

There is a fear that there may be a chilling effect as a result of the language. On the other hand, it provides opportunity to stress abstinence and stable monogamy, which is a basic message that needs to be stressed along with the other things. We are a little uncertain.

Senator WEICKER. Well, let me ask you this question, because I intend to move to remove that amendment one way or another.

Would you be more comfortable with the use of the language——

Dr. MASON. I think that most communities understand basic values and can handle this without Federal legislation.

AIDS EDUCATION FOR CHILDREN

Senator WEICKER. And I want to say this to my good friend, Dr. Windom.

From now on—let me put it this way. I do not profess to in any way match your knowledge and your collective knowledge here on health matters. You have all been trained in that area.

And I think you would also agree not only is that complex enough but then you get into something like AIDS, and that is even complex to all of you who are men of science.

But I think as you also know, this is being fogged up somewhat by philosophical statements of one nature or the other. And I do not think we can afford delays. I do not think we can afford different interpretations on matters of this complexity and this seriousness.

And I would hope from now on when we have legislation on the floor of the Senate, and these matters arise, I am going to put them all on hold until I get ahold of somebody in your Department to explain what the ramifications might be.

Now, I am not asking you to join in what my general philosophy is, and I am not asking you to oppose the general philosophy of somebody else. We are not dealing with philosophy, we are dealing with a very specific matter which has to be addressed, specifically.

So I want to make sure that that does not happen again in the future, and if there is anything you can do to go ahead and eradicate that particular activity.

And while I am talking about that, we will probably get into the AIDS bill next week, S. 1220. And I intend to offer an amendment in that regard that relates to the AIDS education programs for school-aged children.

And while S. 1220 authorizes the training of teachers and parents, it did not call for actual programs to be provided. In other words, specific programs for the children. Because the job as far as parents and teachers are concerned, again, leaves children out.

Now, I really think the time has come, and this is all part of the same thing that we went through on that Helms amendment. I think the time has come to really get some viewpoints here as to what an effective education program consists of.

Because every time we try to do an education program around here, whether it is drugs, or whether it is AIDS, or whether it is sex education, everybody tells me, well, you are teaching homosexuality, you are teaching drug use, you are teaching promiscuity.

That is an interesting argument, but it seems to me that what you are teaching really is how to save a life, or the structure of a life. I am hearing this across a whole range of subjects that clearly relate to you ladies and gentlemen that are here in this room.

And education, especially in the AIDS situation, is really the only tool we have at the present time. And I want your viewpoint as to whether it should be complete.

And let me say this, I am not advocating any sort of an education program that is devised by Chiles and Weicker. This is beyond our view. We are not educators, we are not scientists. Whatever program is devised should be devised by the educators and scientists.

Do you feel the children should be left out of the loop here, insofar as who is being educated? That is my basic question.

Dr. WINDOM. Senator, you are certainly right. We do not feel, however, they are being left out.

I think that given the short-term history of this disease and its impact, the budget for education efforts has increased tremendously. Teachers are responding in very innovative ways with programs in various communities that they feel best inform students and children.

Parents are becoming more aware of this threat to their children, and are becoming more responsible in giving information to their children. In the past we know that many parents avoided even talking about sex education or diseases of children.

The programs we are funding through the CDC are primarily for States to have these funds. They in turn are putting their own money into this area, supporting it, so that we have a combined national-State effort, and I think it is going along very well.

It takes a while to get adapted to this new disease, and I think many States and many people in many schools are doing this.

Senator WEICKER. At what age do you think this education should be transmitted?

Dr. WINDOM. To say categorically any age, I think, is wrong. I think it is the age of the student or the child, at a point when that child is able to understand. That is where I think the parent knows that best, and then his teacher.

Senator WEICKER. Do you agree with the Surgeon General that AIDS education should begin at the lowest grade possible?

Dr. WINDOM. The lowest grade possible and the lowest age possible.

Senator WEICKER. Why do you say this should be up to the parent? Are we not going to give some guideline out there? They do not know, they are not doctors.

Dr. WINDOM. No; but they know what age that child they are dealing with on a one-on-one basis is able to understand the message.

In schools, the teachers understand what grade level is most appropriate, whether it should be third grade, fourth grade, fifth grade, whenever their students can comprehend the information. I think teachers are taking that responsibility well.

So I think AIDS education should begin at the youngest age possible that that person is able to comprehend it.

Senator WEICKER. I had three different schools come down here for the spring break, just this past week, the beginning of the week.

The kids, I would say, were somewhere in the 15, 16, 13, 14, 15, 16, somewhere in those brackets. And somebody asked the question about, you know, what do you think about kids with AIDS attending school?

And I sat there and addressed this matter of, you do not get AIDS by casual contact. I explained as to how in my contacts with the gay community, we all eat together and shake hands, whatever, I tried to personalize it.

They sat there absolutely aghast. They do not know, they do not know, I am telling you, as to how one gets this disease, in terms of casual contact or specifically how, they do not know.

Dr. WINDOM. Well, certainly——

### AIDS MAILER

Senator WEICKER. You know, we can tool around with this thing, you know, we waste 1 month here, and there, and finally getting the AIDS mailer.

Senator Chiles is the one that, he is the guy that was out on the forefront, that was his baby. When did you first propose that? It was 2 years ago, was it not?

Senator CHILES. Yes; 2 years ago.

Senator WEICKER. And nobody would go ahead and listen, and finally we are going to get it out. And I suspect it is going to be a very fine job.

Gentlemen, is there any sense of urgency on this education? I know Fauci and his bunch, and all the rest of them at NIH, they are all going as fast as one can on this matter. I am not worried about that. But what about the education process?

Dr. WINDOM. We are moving fast, and I think this mailer is going to be helpful to really respond to that, because it is going to reach every household, and it is going to be informative, at a seventh grade reading level, and people will have it right on hand, to look at and read.

We can do so much to get to the recipient, and the recipient has to have some response, make an effort to respond. There will be students and children who do not get the message as well as the adults.

But we are doing ongoing information and education activities, and we are increasing the amount spent in this area. Dr. Mason will elaborate on that.

Dr. MASON. I would like to add to what Dr. Windom said. We have now distributed over 1 million copies of the guidelines relative to AIDS education for school children.

These guidelines strongly recommend that AIDS education and information be provided as a component, yes, that is right, as a comprehensive school health education program, kindergarten through high school. It should be under local school board jurisdiction, involving the parents as to the content of the program.

But I could not agree more with you that if you have a child with AIDS in a kindergarten classroom, you need to get to all of those children and explain how this disease is transmitted.

We have been able to not only put out the guidelines, but also grants to national educational organizations like the National Education Association, PTA, and other national groups.

We awarded grants in fiscal year 1987 to the majority of States and communities with high numbers of AIDS cases. During this fiscal year, grants will go out to every State department of education so that they can implement appropriate AIDS education into their school curriculum.

Dr. WINDOM. I might add that the American Academy of Pediatrics also has put out some guidelines on education. They looked from kindergarten to the third grade to talk about germs in general, particularly cleanliness such as washing hands and so forth.

In the third to sixth grade, they start talking about the virus, and about other diseases, so the children would have a little understanding of what causes a disease. Then from the seventh grade on they talk about IV drug abuse, and its association with the virus.

These are guidelines that are out there. Again, the recipients have to respond, but I think it is moving on track. It is not ideal by any means, but I think we are making progress.

Senator WEICKER. I just have this nagging thought in the back of my head, and it is more than just a thought, the philosophy and the moralizing still play a role in how we are approaching this matter.

I realize this is separate and apart, but while you are here, I see that all of a sudden on the matter of fetal tissue, you know, we are going to go ahead and all of a sudden you are taking that one over, and the commission will give you advice.

And I understand that a scientific decision quite clearly has been made in this area. And let me tell you something, just so you understand what happens. A year ago—when was I head of the Bio-Medical Ethics Commission? About 1 year ago. Congress set this thing up.

And this is the matter, would you think that fetal tissue would be a logical one to go into the hands of this ethics group set up by the Congress? We have not been able to move on that commission, as we get into a prolife battle on everything, even the membership of the damn commission.

Mind you, the most significant scientific names out there. Well, how do they stand on the prolife issue? For God's sake, you would not even have had to have a commission on this issue if we were able to go ahead and perform. We cannot.

We are stymied. And I tell you, what a tragedy. And here we are in this business of AIDS, and we have the philosophers out there as to who ought to be taught what, as if those of us that want to get the education across, you know, believe in promiscuity, we believe in homosexuality, and on and on and on. You have got to be crazy.

All I want to make sure is that the kids do not die. Every day that goes by without them getting educated, believe me there is that risk. I do not think one kid should be put at risk. It just makes me furious.

I do not mind a straight up and down vote on abortion. For God's sakes, I mean, we can all do our thing, and I respect somebody's point of view and mine, fine.

But to have it permeate the entire medical-scientific structure of this Nation, and slow it down and in some cases bring it to a dead halt, I think that then we have just about taken this thing as far as it should go in terms of its utility to the lives of the people of the United States of America.

And I just wanted to express this very clearly to you, Dr. Windom, as we sit here and discuss AIDS, I think, only to prove the point as to how dangerous I think it can be.

Let me ask one question and then I will yield to the chairman here. Why do you not go ahead and I will put into order my couple of questions?

### UPDATE ON DRUG DEVELOPMENT

Senator CHILES. I understand a new drug, DDC, is now being used, Dr. Fauci, in connection with AZT to treat AIDS patients. Both of these have toxic side effects.

Give us an update on the effective drugs to treat AIDS patients.

Dr. FAUCI. There are a number of drugs that are now in clinical trials, drugs that are specifically directed against the virus, some drugs that are directed against the secondary complications of the virus, namely what we call opportunistic infections, and drugs that are directed at building up the body's destroyed immune response.

You mentioned two of the drugs. I would just like very briefly to bring you up to date on that. The philosophy of using two drugs like AZT and DDC in combination is that, as you know, AZT has been shown to be effective in prolonging the lives of individuals with advanced HIV infection.

There are two things that are going on simultaneously with AZT. First, it is being used in earlier and earlier infections.

The first AZT studies were studies of people who had AIDS and opportunistic infections. It is now being studied alone in individuals with AIDS and Kaposi's sarcoma, and AIDS-related complex, or ARC.

We have another study that is quite important: the use of AZT in asymptomatic carriers of the virus. In other words, individuals who are perfectly well, have no symptoms yet, except that they are infected with the virus. This is a 1,600 patient study that is being executed now in our AIDS clinical trial group. That is one approach; what we refer to as early intervention.

Another approach is the use of drugs in combination with other drugs. The one you mentioned is a very good example of using two drugs, AZT and DDC, alternatively. One week of AZT, one week of DDC.

The rationale is to try to obtain the maximum efficacy while minimizing the side effects. If you give the body a rest from AZT, while you are giving DDC, it will recover. The suppression of the bone marrow and other toxic complications will be minimized.

And then there are a variety of other drugs. In all we have six antiviral drugs in clinical protocols throughout the United States; four drugs for biological response modifiers, and five drugs against opportunistic infections.

In the NIH Government-sponsored trials, there are now approximately 3,500 people involved in 22 protocols that are still active, 5 which have been closed because the number of patients projected for the trial have been accrued.

There is a very active clinical trial program going on with a number of drugs that are being tested.

### STATUS OF 1987 EMERGENCY SUPPLEMENTAL

Senator CHILES. Dr. Windom, as you know, we appropriated $30 million in the 1987 supplemental for AZT, that was a one-time emergency supplemental.

Funds were made available to States in September 1987. We did that on the basis that we brought certain people in to treat, and in part of our experimentation we were doing, and that we should try to provide a carryover for them.

I understand California, Minnesota, Texas, and Puerto Rico have not used any of their funds to date. In view of the emergency, why is it that a State like California has not used any of their money?

Dr. WINDOM. Those States that have not had funds from other sources, from Medicaid or their own internal funding, have not necessarily needed the supplemental amount. The emergency funds were given to States that were not able to meet the demand from other sources.

### HIV-2 VIRUS

Senator CHILES. Dr. Fauci, in addition the HIV–1 virus, we now have seen this HIV–2 identified in Africa and France. Is the genetic code for this sufficiently different from HIV–1 that a vaccine or therapeutic drug developed for one would not work on the other?

Dr. FAUCI. It is sufficiently different for us to be calling it a different virus. It is so different that, in fact, a vaccine against one will almost certainly not protect against the other.

But, the therapy that uses the blocking of certain viral enzymes, one of which is reverse transcriptase, has in preliminary studies been shown to block HIV–2 as well as it blocks HIV–1.

So the differences in the structure of the virus would have much more relevance with regard to the body's ability to recognize it and protect against it, and less relevance with regard to a drug that it is developed against.

Senator CHILES. Should we be working on a vaccine for HIV–2?

Dr. FAUCI. At this point, no. So little is known about the appropriate immune response against HIV, that we need to tackle the HIV–1 problem in a systematic, methodical way.

Once we establish what the effective immunity against HIV-1 is, it will not be, in principle, significantly different from what HIV-2 will be. We will need a separate vaccine development, but it would be developed along the same philosophical lines.

In this country there is no HIV-2 disease at the present time. We have only had one reported case of a West African woman who moved from West Africa to New Jersey, who was ill with HIV-2.

The prevalence of the infection in this country is at this time essentially zero, even though we are still obviously concerned about monitoring the situation.

Senator CHILES. Knowing that we are going into the genome studies and that we are trying to unlock the code, and we are going to be putting some money in the bill, are we at Los Alamos, at NIH, and every place that we are doing these, are we looking to try to get into that portion of the code that would affect AIDS initially?

In other words, we have got 3 trillion pairs or something that we have got to try to work on before the thing is over, and we know we are talking about from $3 billion to $11 billion, people's estimates of what it will take. Are we concentrating to try to understand those parts——

Dr. FAUCI. It would only be indirectly, because the 3 billion base pairs that you are talking about refers to sequencing the entire human genome, which is different from the genes of the virus.

But all molecular biological studies that try to determine the relationship between a particular gene and the function of that gene will have relevance in crosscutting ways.

So although when you sequence the human genome, that is, will not tell you very much about the gene of the virus. We do know that as we——

Senator CHILES. So there is no way, what you are telling me is there is no way to concentrate on a portion of the human genome and say we are going to lift that out, it crosses too much.

Dr. FAUCI. Right. But there is one part of the human genome that will have relevance to AIDS, and that is the part of the genome, the human genome, that controls immune responses.

Senator CHILES. I see.

Dr. FAUCI. You see, for example——

Senator CHILES. And are we concentrating on——

Dr. FAUCI. Oh, absolutely. In fact, of all the parts of the human genome, the part of the genome that is relevant to the direction of the body's immune response is one of the most well studied.

It is part of the gene related to the human lymphocyte-endogen, which we call HLA. And that is the area that is very relevant to how the body responds to a particular viral or bacterial protein.

## PEDIATRIC AIDS

Senator CHILES. Dr. Windom, you showed us these charts on the pediatric cases of AIDS. And one of the special problems we face is the compassionate care for these babies.

We are now beginning to hear about the boarder baby crisis. That mother that decides she cannot take care of her child, so she just leaves it or abandons that baby.

Of course, where they are in our hospitals, those costs are phenomenal. And very high, and probably that child is not getting the kind of love and affection and attention that they need to rely on that.

Last year the committee provided $4,787,000 to demonstrate ways to help these children, other than hospital-based care. What alternative types of managed care are we looking at now?

Dr. WINDOM. One area that has been particularly well received, and we are encouraging more of, is foster care. More people all along are volunteering and taking these infants out of the hospital setting.

Also, they are outside of the hospital environment, in homes where they may take in three or four or five infants, where one or two people will help manage them.

So this is a very strong effort and we are trying to get more people to look at this type of care.

Senator CHILES. I would like to see some kind of——

Dr. WINDOM. We could give you a breakdown on that.

Senator CHILES. I would like to see those and what those studies show.

Dr. WINDOM. OK.

Senator CHILES. Knowing that the highest incidence of this pediatric AIDS fall on black and Hispanic populations, are grant dollars going to those areas with a high incidence of those populations?

Or let us say the pediatric AIDS, which has to go to the populations?

Dr. WINDOM. We do not know exactly the breakdown at this point, but our pediatric AIDS task force is looking into that issue also. They are just underway, and I will have the report in October of this year. But we are focusing on minorities in particular.

Senator CHILES. Well, expressly, looking at the number of children with AIDS that we are going to face in 3 years, do you think $5 million is an adequate amount to set up special care services?

Dr. WINDOM. This is the amount we have proposed and we feel that is adequate. We will see what the response is as we go on to service delivery options and alternate-type care.

## NATIONAL SEROPREVALENCE SURVEYS

Senator CHILES. Dr. Mason, the Centers for Disease Control plan to measure AIDS infection rates for the general U.S. population.

Included within your request is $72.9 million for national seroprevalence surveys. Last year we appropriated $10 million and you told us that your requirement might grow to $17 million.

Why do we see a $63 million increase, when you told us it might go as high as $17 million?

Dr. MASON. Actually, during this current fiscal year, we will be spending almost $46 million to carry out national seroprevalence surveys. We are absorbing that in our 1988 budget.

Then for the fiscal year 1989, that will go up to the figure you quoted, $75.5 million. Because of the agreement that there will be no supplemental in fiscal year 1988, we have done some redirecting of the budget.

We are actually not funding our State grants for a 12-month period. We are funding the grants to the States at the same level they would have been funded, but we have had to reduce the grant period to 8 months so that we could accommodate first the seroprevalence survey, and second some expenditures related to the mailout.

Senator CHILES. Did you seek a reprogramming from us to spend more money on this survey?

Dr. MASON. We have conferred with the Public Health Service, and it was recommended that we handle it that way. It was handled through a letter to the Appropriations Committees.

Senator CHILES. It seems like if we thought you were going to spend up to $17 million, and we appropriated $10 million, and now you are taking money from other places to do this sort of household survey that I understand there are some problems about knocking on somebody's door and telling them you want to take some blood sample for AIDS, I am just kind of wondering——

Dr. MASON. This is much more than a household survey. We are not sure that——

Senator CHILES. Are we not supposed to be in on that?

Dr. MASON. As I say, the only way we could handle the family of surveys, the special surveys, and do the pilot phases of the random household survey, was to use money that existed in the budget.

After conferring with the Public Health Service, and HHS, we sent letters saying that this is the way we were going to handle that problem, and have moved, I would say, vigorously ahead to get the information that we need on the number of infections that——

Senator CHILES. Well, I find it a little strange, Dr. Mason, that when this committee or the Congress wants to do something, and we put in money for an AIDS mailer, we can see that delayed over 1 year, and the money not used.

But when someone, and I assume the White House or something decides they want a survey, then we take money from everywhere else, and the Congress does not participate in that. It sounds a little, I do not understand how that works. Maybe I do not have it right.

Mr. LITTLE. Our 1989 request includes $22 million first-time money for the national household seroprevalence survey. That is something that we are coming to you and asking your permission to do.

The pilot household surveys were for much less money—about $2.6 million. We are planning to initiative those in 1988. But if this committee says, we should not initiate the pilot surveys, we would certainly respond.

Mr. FORBUSH. The survey has not been delayed. It has to go through several stages. We are at the stage of really doing a kind of feasibility of the national sample, and that has proceeded on schedule.

Senator CHILES. Well, we will get a chance for the committee to, and our staff to look into this, and to understand this a little better.

Dr. MASON. The household survey is $2.6 million in fiscal year 1988, and if it can be done it will cost $22 million in fiscal year 1989, and that is in the fiscal year 1989 budget.

## IV DRUG ABUSE FUNDING

Senator CHILES. The President's AIDS Commission issued an interim report, and made a number of recommendations, including $1.15 billion be spent each year for the next 10 years for a vast expanded treatment for IV drug users. Funding is split between Federal and local governments.

Your request included $40 million for IV drug treatment demonstrations. The President's Commission is going to issue its final report this June. We would like to have your reaction to the first series of 100 plus recommendations. Are we spending enough on the IV drug treatment?

Dr. WINDOM. First of all, on the 178 recommendations that they have given in the interim report, we have looked at those and are getting responses from our agencies as they apply to a particular agency or to several agencies. We will have that report very soon.

Now, as far as the drug abuse treatment situation, we do have some interesting figures. I would point out that in 1987, when the first block grant funding for the drug abuse treatment programs was given to States, only 33 percent of that money has been drawn down. This is because States have to look at how they are going to set up the treatment centers, get the personnel to staff them, and get the programs established. The Federal dollars that are there now have not been completely utilized.

We feel right now that the amount of money that is there is sufficient, and that the States are adapting as well as they can and as quickly as they can. We know there is going to be increased amounts needed. But the exact figures on that needs to be evaluated.

Senator CHILES. Well, we would like to have your recommendations as those come through. Senator Weicker?

Senator WEICKER. On that point——

Ms. BYRNES. It is my understanding that by the end of fiscal year 1988, all those moneys had been obligated.

Many of the States have not drawn down the money, but it will be spent. And in particular, the State of Connecticut has used its allocations. So there are many States that have actually used their money.

Dr. WINDOM. At this point, 51 percent has been obligated, as of March 14 of this year. Connecticut, I believe, has outlayed 42 percent as of March 14. We will give you copies, if you would like.

## EFFECT OF AIDS BUDGET ON NON-AIDS BUDGET

Senator WEICKER. Dr. Windom, obviously I was pleased to see the increase in funding as related to various AIDS activities.

On the other hand, what I would like to know is, in order to achieve these levels of funding, did the AIDS allocations, specifically just the AIDS allocations, require cutbacks in other areas?

Or was it, as was suggested by the National Institute of Medicine in their report, new money that you people were drumming up for AIDS?

Dr. WINDOM. In the present budget request, if you take AIDS out entirely and look at the rest of the NIH budget, it increased 5.4 percent for all other non-AIDS-related research activities.

It has even exceeded the Gramm-Rudman target of 2 percent. There has been a continuing escalation of funding in this particular area.

Senator WEICKER. Well, how is it that cutbacks took place in health professionals training, and childhood vaccination programs?

Dr. WINDOM. Vaccines, I believe, were not cut back.

Senator WEICKER. There is no vaccine stockpile, and eliminated all administrative costs.

Dr. WINDOM. The stockpile is not up to its full complement, but I believe it has been conpleted to about two-thirds of the planned complement.

Mr. LITTLE. In the 1989 request, we did not ask for funds for the stockpile.

But in 1987 we spent two times our normal annual level, if you will, about $7.4 million. Also with the new legislation, there was some thought that in 1989, we would not ask for money for the stockpile, hoping that there would be additional manufacturers and lower prices.

Senator WEICKER. What is the situation vis-a-vis the stockpile?

Dr. MASON. We have not reached the Nation's target of the 6 months of vaccine in the stockpile.

Dr. WINDOM. It is less. Approximately two-thirds of the complement or 19 out of 26 weeks, I believe by the end of 1988.

Senator WEICKER. What about geriatric training? Was that not zero funded also?

Dr. WINDOM. It was included in a consolidated grant program for health professions.

Senator CHILES. What will it cost to reach a stockpile in 6 months?

Dr. MASON. It would cost about $36 million, if we were to complete a 6-month supply of all the recommended vaccines for children.

Senator CHILES. That is $36 million in addition?

Dr. MASON. In addition to what we have put into it thus far.

## HEALTH PROFESSIONS SHORTAGES

Senator WEICKER. So in effect, in any event, it is safe to say, obviously, that there are some programs that are—I certainly do not think, just to take two, either under the spectrum, or anybody is going to deny that, No. 1, we need to stockpile it for the kids.

No. 2, considering the figures coming over the Hill at us, in terms of the elderly, we better start to train some doctors in nursing homes.

Dr. WINDOM. Well, the care for the elderly is going to increase with the increased number of elderly people. But I think the medical complement is there, particularly in the physician surpluses. They are now at a level adequate to be able to take care of the elderly.

The nursing problem is one that is being approached very actively right now with the Nursing Commission, which will have their report this fall. They are analyzing the total——

Senator WEICKER. All across the country, every report that I read is that we are either in a moderate, depending on the area, either a moderate to a serious shortage.

Dr. WINDOM. In nurses? That is the overall perception at this point. But this is——

Senator WEICKER. And also for those that are equipped, both nurses and doctors, in terms of taking geriatric training, again we are going to be, when this really hits is the year 2000. That is when you have got your doubling of your over-85 population in about the year 2010. And there is going to be a severe shortage as far as both doctors and nurses are concerned.

Dr. WINDOM. Well first, Senator, I want to point out that——

Senator WEICKER. How long did it take you to get all your medical training behind you? How many years?

Dr. WINDOM. Well, most physicians are about 30 years old when they finish. Maybe even a little bit older, in some specialties.

Senator WEICKER. It is only 12 years away, and we are ill-prepared to go ahead and handle it.

Dr. WINDOM. I want to point out, though, Senator, that the doctors being trained in a medical program are trained to handle people to their terminal age, whatever that may be.

It happens that we have a concentration of them at that point. But the medical management and the care is not that greatly different from that given during younger life, except for maybe some alternate types of drug treatment.

Physicians and nurses have cared for people in their elderly years for a long time. There are just going to be more of them to take care of. However, physicians and nurses will be adequate through medical education and continuing programs to handle the very specific needs that are there.

## AIDS FACILITIES FUNDING

Senator WEICKER. In 1980, Congress appropriated $23,935,000 for an extramural AIDS research facilities improvement program.

How much has the NIH requested for this program for fiscal year 1989? And how much have we spent on primate centers?

Dr. FAUCI. I would have to supply that for the record.

[The information follows:]

### NIH FISCAL YEAR 1989 AIDS FACILITIES FUNDING AND PRIMATE CENTERS FUNDING, FISCAL YEARS 1982–89

For fiscal year 1989, the NIH has not requested funds for the extramural AIDS research facilities improvement program.

To date, the NIH has obligated the following amounts for primate centers:

| Fiscal year: | |
|---|---|
| 1982 | $100,000 |
| 1983 | 295,000 |
| 1984 | 858,000 |
| 1985 | 1,789,000 |
| 1986 | 4,933,000 |
| 1987 | 6,409,000 |
| 1988 | 10,174,000 |
| 1989 request | 17,116,000 |
| Total | 41,674,000 |

### INTRAMURAL AIDS FACILITIES

Senator WEICKER. Let me ask another question, Dr. Fauci. As you know, I requested last time $19 million, and the request was acceded to by the Appropriations Committee for intramural AIDS facilities at the NIH campus.

How have these funds been spent? And has the appropriation alleviated the space concerns that were brought to the attention of this committee last year?

Dr. FAUCI. I could give you the exact details for the record, but I can tell you right now that the money has been extremely helpful in alleviating a very serious problem that we have had at the NIH, both in the intramural program, but also in being able to house and facilitate the spending of extramural money by our programs.

When we expanded the AIDS program at the NIH, we had to bring on a large number of people, and we really had no place to put them. And the money for the intramural and intramural research facility expansion, as well as the expansion for the extramural staff to administer the extramural grants, has been greatly alleviated by that money.

### AIDS HOME TEST KITS

Senator WEICKER. Dr. Windom, you and Dr. Fauci and Dr. Mason, how do you all view the matter of AIDS test kits for use at home?

Dr. WINDOM. Dr. Parkman is here from FDA. This has been looked at considerably in great detail by FDA, and presented to our AIDS task force under the Public Health Service.

We have looked at this issue, and I would ask him if he would comment on the specific recommendations.

Dr. PARKMAN. I think that the perception that we have closed the door on home test kits is not correct.

What we indicated is that we had serious concerns about proceeding with over-the-counter test kits, because of our concern among others that adequate counseling be given to people.

So what we did initially, was to tell people who are interested in marketing these testing systems that individual users should have the speciman obtained by a medical care provider. Then the speciman would be mailed to the testing service. The results would come back to the medical care provider who provide the test results to the patient and provide counseling.

At the same time we said that we felt this was a difficult issue, and that we planned to publish a Federal Register notice, indicating the nature of the problem for public comment.

We also plan to have a public meeting in which these issues can be discussed fully, and gather points of view about the feasibility and the ethical and other issues that are involved in the marketing of these kinds of test systems.

Senator WEICKER. I gather there is nothing unsafe in the use of the test.

Dr. PARKMAN. No; we have asked that the actual test to be used must be a test that is approved, or equivalent to an approved test that has already been licensed by us.

For example, the ELISA and the western blot tests that are already approved be used in testing.

Senator WEICKER. In other words, there is nothing in the test itself that could prove to be dangerous to the individual utilizing it.

I am not talking about the ramifications of the results. I am talking about the test itself.

Dr. PARKMAN. That is correct. There is nothing inherently dangerous if the specimans are appropriately collected, shipped, and carefully tested. I think the concerns are directed to the results of the test being presented to the individual, and the counseling and maintenance of confidentiality.

Senator CHILES. Which all comes in, I guess, to the fact of how accurate still the test is. The positives and the false positives, all of that. And then the psychological effects and mental effects that come from that.

## CHEMOTHERAPY APPROACH TO AIDS

Senator WEICKER. You commented on the vaccine situation. Where do we stand on the chemotherapy approach toward the problem?

Dr. FAUCI. There are two parts of that. There is the drug development program, and the clinical trials program.

The drug development program, with the national cooperative drug discovery groups, the money that was appropriated to Office of the Director of NIH for the structural biological programs, intramurally and extramurally, are coming along really very well.

In fact, just since the program was initiated this past year, three candidate agents have been developed which are now being evaluated to go into clinical trials.

The clinical trial program is really moving. As I had just mentioned, there are about 3,400, 3,500 individuals in trials. Ten antiretroviral agents alone are in combination being used in clinical trials, 22 protocols that are still active, 5 that have been closed because enough patients are in them.

And we are now taking a much closer look at getting community research initiatives involved. In fact, we have met with the community research initiative people from New York and San Francisco, and are getting involved in trying to bring the people who are in the outside community more involved in the trials.

So there really is a lot of activity, both on the development and on the clinical trials areas.

### NEW DRUG DEVELOPMENT

Senator WEICKER. How long before you feel there will be some product out there that can significantly halt the progression of the virus?

Dr. FAUCI. There is already one out there, Senator, but the difficulty with it, as you are well aware, is that there is considerable toxicity, and not everybody responds to is, and that is AZT. And that is the reason to work with the combinations.

For example, AZT and DDC, or now we have a study that we just completed that looks quite favorable with alpha-interferon use in patients with Kaposi's sarcoma, in which we now have shown that alpha-interferon not only causes complete and partial remissions in the Kaposi's sarcoma but also has a significant antiretroviral effect. So now we are combining alpha-interferon with AZT, both in early patients as well as in asymptomatic carriers.

I cannot give you a date, but I would imagine that we are going to be able to have improvement on what we have now vis-a-vis AZT alone within the next year or two, so that we would have a drug that will not cure AIDS, we do not think in terms of cure, but would suppress it enough so that someone could lead a meaningful life.

It is going to be different for the stage of the disease, early disease, asymptomatic carriers, far advanced opportunistic infections. But I think we are talking about something that certainly is in the foreseeable future, which is in contrast to what I mentioned about vaccine where it is going to be well into the 1990's.

Senator WEICKER. Thank you.

### PATIENT OUTCOME RESEARCH

Senator CHILES. Doctor, leaving the AIDS area, and we will have some other written questions on that, studies have shown in one area of Maine, by the time a woman reaches the age of 70, it is 70 percent likely that she has undergone a hysterectomy and in the area of the State the likelihood is only 25 percent.

One of those reasons seems to be the lack of sufficient knowledge to guide clinical decisions. Last year we appropriated nearly $2 million for research for patient outcomes. However, this year you have dropped any funding for this request in your 1989 request. Why is that?

Dr. WINDOM. Continuing the studies for the outcome has been ongoing, and I would like to ask Dr. Fitzmaurice, who is directing this under the National Center of Health Services Research, to elaborate.

Dr. FITZMAURICE. Could you repeat your question please, Senator? You were asking about the $2 million appropriated to the National Center?

Senator CHILES. That is right. Last year, we gave you $2 million to research on patient outcome. This year there is no funding in your budget for that. You know the problem has not gone away.

Dr. FITZMAURICE. That is correct. It was decided that in lieu of the Department requesting trust fund money in fiscal year 1989, a request for $15 million would be included in the HRSA budget for health care improvement. This will allow us to research the entire population, not just the Medicare population, which funding from the trust funds would limit us to.

Dr. WINDOM. This program will be in the HRSA budget, and NCHSR will be involved in the program to help carry out the studies and evaluaton of patient outcomes.

### HEALTH SERVICES RESEARCH

Senator CHILES. I want to ask you about health services research, the level of funding there.

We think that health services research is useful in streamlining and standardizing our health care delivery in this country. You have asked the level of funding, that budget request for the National Institutes of Health without AIDS funding, reflect a 5.4-percent increase.

More dramatic is the 19-percent increase in the research budget for HCFA. As far as I understand, you and HCFA both conduct applied health services research. You are requesting $16.8 million for 1989, an increase of $196,000, 1 percent over last year's appropriation of 16.6 percent.

Why do other agencies fare better in your health research funding increases than research in health services delivery?

Dr. WINDOM. The aspect of the health services deliveries in HCFA is an important part of their program, and HCFA and the Public Health Service collaborates in looking at research on health care delivery from both our standpoint as well as theirs.

We have representatives from both of our divisions working together with the funds coming from the HCFA trust fund, and from our own directly appropriated funds to NCHSR, as well as funds from other agencies.

This year, for example, in 1988, we went from $1 million to $9 million for the 1989 request for NCHSR, just for the AIDS research, and delivery services.

Senator CHILES. You have got a lot of other problems of health care delivery.

Dr. WINDOM. I would like just for the record to point out that it has only been 4 years since the AIDS virus has even been identified.

With the rapid advance in science that we have had, all this drug and vaccine development could never have happened had we not had prior to that a very good scientific infrastructure, federally as well as academically.

Senator CHILES. I know that is true. I think you all are to be congratulated.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

There will be some additional questions from various Senators which we will submit to you for your response.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## PROGRESS IN AIDS RESEARCH

Question. Last year we discussed a poll of 227 scientists, 46 percent of which felt that we would have a vaccine by the year 2000.

I know you currently have clinical trials underway to test two vaccines on a group of 81 people. What progress is being made to find an effective vaccine?

Answer. The first AIDS vaccine trials have already begun. These first tests are called Phase I, and are testing the safety and immunogenicity of experimental AIDS vaccines in small numbers of volunteers. The first product to be tested is known as gp 160, which is a protein of the AIDS virus engineered by recombinant DNA technology. This product is being tested both at the NIH Clinical Center and at the NIAID Vaccine Evaluation Units. The preliminary data that we have from these studies indicates that the product has not produced any significant adverse reactions, and induces antibodies directed against the gp 160. The volunteers in these trials are healthy adults, who are HIV seronegative and not at high risk for HIV infection. We anticipate that other experimental AIDS vaccines will be tested at the Vaccine Evaluation Units in the near future.

Vaccine development efforts are proceeding rapidly, with industry, academia, and government scientists collaborating on a variety of approaches to AIDS vaccines. As the agency of the PHS with the lead responsibility for AIDS vaccine development and evaluation, the NIH generated an AIDS Vaccine Plan to create a framework for insuring that all steps in the vaccine development process will be addressed, and that vaccine development will only be limited by the rate of scientific progress in basic research. The major points of the plan are that it:

- provides for a comprehensive strategy for AIDS vaccine development
- minimizes disincentives to vaccine innovation and production
- utilizes innovative approaches to foster collaboration between government, industry, and academic scientists
- provides for a network of national resources to facilitate AIDS vaccine development
- provides for a coordinated and flexible system to review and set priorities for resource allocation
- provides for technology transfer, reagent production and standardization, and information exchange

Although formidable challenges still remain on the path towards a safe and effective AIDS vaccine, progress in understanding the immune response against this virus continues to provide scientists with clues toward designing a successful vaccine.

Question. What is the research strategy, Dr. Fauci? Has the focus shifted away from finding a cure, or do you still hope to find a true cure?

Answer. While no one can ever reliably predict that a cure will be found, there is good scientific reason for believing that significant therapeutic advances can be achieved over the next few years. A number of animal studies have shown that we can successfully treat animals infected with viruses closely related to the AIDS virus. Other animal studies have shown that drug treatments can successfully prevent transmission of viruses closely related to AIDS from mother to offspring.

There is an enormous amount of preclinical work going on in laboratories at NIH, in the pharmaceutical industry, and in academic institutions throughout the United States to find new therapies for AIDS. We have research underway attempting to identify a drug that interferes at each step of the virus life cycle. We believe it likely that a combination of drugs targeted at different aspects of the life cycle of this virus can be found. Moreover, a number of promising drugs are already in the pipeline for development.

The achievement of a cure would be the ultimate success of AIDS therapeutic research, and consequently will always remain our goal. No one can say for sure whether we will achieve it, but the intense effort of many scientists now working on AIDS therapies offers the best prospect for achieving this goal.

## PRESIDENT'S COMMISSION ON AIDS

Question. In February, the President's AIDS Commission issued an interim report that made a number of recommendations including that $1.5 billion be spent each year for each of the next ten years for a vastly expanded treatment program for IV drug abusers, funding split equally between Federal and local governments. Your 1989 request included $40 million for IV drug treatment demonstrations.

The President's Commission will issue its final report this June. What is your reaction to the first series of 100 plus recommendations? For example, are we spending enough on IV drug treatment?

Answer. The Public Health Service has done some initial analysis of the Interim Report recommendations, but await the final Commission report to do a detailed analysis of the recommendations in final form. As part of this review process, several options for addressing the problem of intravenous drug abuse and AIDS are being considered, including demonstration and outreach programs, interventions designed to reduce HIV transmission, as well as treatment expansion.

## AIDS DRUG TREATMENT

Question. We hear that there may be some problems with a rapid buildup of drug treatment programs, such as community resistance to the location of new facilities, lack of trained treatment staff, and the difficulty of recruiting drug addicts into treatment.

What do you think is the maximum amount of funding that could be spend responsibly for drug treatment in FY 1989, assuming that the Federal government picked up half the expense?

Answer. Currently, both the Commission recommendations and internal budget proposals (both for FY 1989 adjustments and for FY 1990 budget development) raise this issue, and we expect that policy and spending amounts will be determined soon. Obviously, the start-up issues that you mention (lack of trained staff, difficulty in locating new facilities, etc.) will affect Federal and State government's ability to increase drug treatment rapidly.

Question. Who is managing or coordinating this overall Federal effort?

Answer. No one group, task force, or coordinating body is managing all of the monies requested for programs outside the PHS. However, there are several ongoing groups and coordinating bodies which oversee much of this Federal effort.

In 1986, the position of PHS AIDS Coordinator was established in OASH to act as the principal advisor to the ASH on all issues related to AIDS and to coordinate all PHS activities aimed at the prevention and control of AIDS. In addition, the AIDS Coordinator informs the ASH of emerging issues which may require his personal attention and serves as the principal focus for all AIDS activities.

A number of mechanisms have been established in the PHS to assist the AIDS Coordinator and the ASH to respond to the growing dimensions and impact of this disease, and several new steps are being taken to enhance the ability of the Office of the AIDS Coordinator to respond to the rapidly increasing demands for information necessary to keep abreast of all of the developments related to AIDS.

- The PHS established a Federal Coordinating Committee on AIDS Information, Education, and Risk Reduction in December 1986. The Committee is composed of seven Federal departments (USDA, DOD, DOED, HUD, DOJ, DOL, and DOS), six independent agencies (Action, AID, EPA, OPM, USIA, and VA) and three offices within the Executive Office of the President (Domestic Policy Council, Office of Management and Budget, and Office of Science and Technology Policy). The departments and agencies all have constituencies, networks, and issues which make them crucial actors in government-wide AIDS information and education efforts. The committee meets once a month, shares information about AIDS activities of the various agencies, and identifies government-wide policy issues and needs for AIDS information, problems and goals of the critical public health efforts on AIDS.

- In the fall of 1987, the Secretary established an HHS Task Force on AIDS, which is chaired by the ASH. The Task Force membership includes the ASH, the PHS AIDS Coordinator, the Under Secretary, and OS Assistant Secretaries and Directors of OS staff offices. At the weekly meetings, information about ongoing and new AIDS initiatives is shared, policy issues are addressed and recommendations are often made regarding specific AIDS initiatives to be undertaken by one or more of the organizations represented at the meeting.

- In November 1986, at the request of the Assistant Secretary for Health, an intragovernmental Task Force on AIDS Health Care was created. Dr. David N. Sundwall, Administrator, Health Resources and Services Administration, served as Chairperson. The responsibility of the Task Force was to look at how health care is currently being delivered to AIDS patients and those individuals with HIV-related conditions and what other health services may be required, with particular emphasis on the quality of care, access, financing, integration of Federal, State and local roles; and the family. A report has been submitted to Dr. Windom containing recommendations for appropriate Federal, State and local roles and partnerships in addressing the identified needs. The ASH has designated agencies/ administrations to implement the recommendations.

- At this year's appropriations hearings, the Administration proposed centralizing funding for the PHS AIDS effort in the Office of the Assistant Secretary for Health. The President's budget request for PHS AIDS activities in FY 1989 is $1.3 billion. If this request is enacted into legislation, responsibility for AIDS budget formulation and execution will also fall under the aegis of OASH, with NAPO being the immediate effector arm. Additional positions will be needed to carry out these responsibilities.

- The rationale for requesting all AIDS funds to be consolidated under a new account in the OASH includes: flexibility to meet changing requirements by allowing PHS to manipulate resources to meet emerging needs with greater ease; greater coordination across the agencies of PHS; and an increased degree of visibility for AIDS in the budget.

## PHS AIDS ADVISORY COUNCILS

Question. Additionally last year the Committee asked that Advisory Councils for each Public Health Service Agency be established and a Secretary Coordinating Board be established at the Department of Health and Human Services. Have these bodies been established?

Answer. HRSA, ADAMHA, and CDC have charters prepared and in various stages of progression all having been submitted to Committee Management, GSA. Dr. Young is in favor of the formation of an advisory committee and FDA is currently discussing details within the agency. NIH has established an AIDS Advisory Committee for which Dr. Wyngaarden serves as Chairman. Its first meeting will be held July 12.

Question. Last year we gave the Secretary the authority to reprogram AIDS funds. I was surprised to see that wasn't used, especially as the unique problem of pediatric AIDS became understood.

Should we continue that authority or do you think that a contingency fund is a better way to handle unforeseen events?

Answer. PHS has no used this authority due to the fact that no agency has requested additional AIDS resources; however, if any unforeseen emergency should arise, we would not hesitate to request a reprogramming of resources.

Our FY 1989 proposal for a contingency fund and authority to transfer up to 3 percent from any PHS appropriation will afford us a funding mechanism to provide immediate allocation of resources in response to any urgent request for additional AIDS resources.

## TRUE FUNDING NEEDS

Question. We know that OMB very uncharacteristically increased your AIDS budget from $1.145 billion that you requested to $1.3 billion. These adjustments were made in January.

Since then, and also since last September when you made your request, have things changed to suggest the need for more funding?

Answer. I have not received any requests for funding. I must add that in mid-March, I received a request from FDA for an urgent unbudgeted item related to the safety of the nation's blood supply. As you know, a $15 million contingency fund is being requested for such emergencies that may arise in FY 1989. The FDA request provides an illustration of that need for greater flexibility. Without the authority, several months could be lost in development and consideration of such proposals within both the Executive Branch and Congress.

## HIV-1 VERSUS HIV-2

Question. The AIDS cases identified in the United States are associated with the HIV-1 virus. But I understand that another strain of the virus--HIV-2--has been identified in Africa and France. Please tell us the scientific community's assessment of this new AIDS virus. Is it likely to spread in the United States?

Answer. HIV-2 was initially recovered from a West African patient with AIDS. Infection with this virus produces a clinical syndrome that is indistinguishable from HIV-1-induced AIDS. So far, there has been only one confirmed case of HIV-2 in the United States. This is in a 41 year old woman who contracted the virus in West Africa, came here for treatment, and to the best of our knowledge, has not spread the virus to any other contacts. The Centers for Disease Control have screened over 25,000 people in this country, in both low risk and high risk groups, and have not found any people seropositive to HIV-2. However, one cannot dismiss the potential for spread of this virus, and the Public Health Service will continue to monitor for any such spread.

Question. Can it be detected in the blood supply by tests currently conducted for the HIV-1 virus?

Answer. No, unfortunately not. The currently-approved blood test kits for the detection of HIV-1 (ELISA and Western blot) cannot be adequately relied on to detect the presence of the HIV-2 virus. Although studies of HIV-2 are ongoing, FDA has received and is currently reviewing only one license application for a blood test kit to detect HIV-2.

Question. Is the genetic code for the HIV-2 virus sufficiently different from the HIV-1 virus that a vaccine or therapeutic drug developed for one wouldn't work for the other?

Answer. The major emphasis of vaccine development at the present is on the envelope glycoprotein of the HIV. These proteins of HIV-1 and HIV-2 are only about 40 percent homologous, with some but not complete cross-reactivity. It is too early to tell whether or not individual vaccines (or drugs) would be required for the two viruses. Theoretically, if conserved regions of the viruses could be targeted for chemotherapeutic or prophylactic intervention, there might not be the need for individual products against the two viruses. However, if the conserved regions of the viruses were not accessible, then the likelihood for a single antiviral or vaccine to be effective against each virus would diminish. A tremendous amount of research into the genetic variation of HIV is supported by NIH.

## PEDIATRIC AIDS

Question. By 1991, in less than 3 years, researchers project that 3,000 infants and children will develop AIDS, and that 10,000-20,000 more will test positive for antibodies to the virus.

One of the special problems we face is the health and compassionate care of these children. We have all heard about the "boarder baby" crisis, where mothers are unable to care for their infants and rely on the hospital to take care of the child.

Last year, this Committee provided $4,787,000 to demonstrate ways to help these children other than hospital-based care.

What alternative types of managed care are we looking at?

Answer. The new Pediatric AIDS Health Care Demonstration Grants will provide or enhance existing specialized ambulatory health services emphasizing case management. The provision of family-centered, community-based coordinated care; coupled with day care; respite care; and, if necessary, transitional group foster care has been demonstrated to be effective in returning "boarder babies" to family care.

Question. Statistics show that pediatric AIDS cases fall disproportionately on the Black and Hispanic populations. Will these grant dollars to areas with high incidence of pediatric AIDS? Will the local communities be involved with the coordination of these demonstrations?

Answer. Most applications for the new FY 1988 Pediatric AIDS Health Care Demonstration Grants is are being submitted from the geographic areas with the greatest number of infants and children with HIV infection and AIDS. The Maternal and Child Health program has been working closely with these communities to encourage joint planning at the community level and collaboration and coordination with all other AIDS related programs in the community. The PROGRAM GUIDE for Applicants states this and it has been emphasized in all the technical assistance efforts, including two Workshops where community groups were brought together.

Question. Looking to the numbers of children with AIDS that we will face in just three years, do you think that $5 million is an adequate amount to set up these special care services?

Answer. The basic purpose of these grants is to establish demonstration projects and models. The President's FY 1989 Budget proposes secretarial transfer authority which would permit us to access resources more effectively in cases like this. We will certainly keep you and the committee advised.

FUNDING FOR AZT

Question. Dr. Windom, as you know we appropriated $30 million in the 1987 supplemental for AZT. This was a one-time emergency supplemental and the funds were made available to the States in September of 1987. We understand that California, Minnesota, Texas and Puerto Rico have not used any of their funds to date.

What can you tell us about this situation? In view of the emergency, why in a State like California hasn't any of the money been used?

Answer. All of these States have operational programs. However, some were slow to start and only became operational by early February 1988. The State of California, whose program began in mid-October 1987, set its low income eligibility criterion too close to Medicaid qualifying levels, which also pays for Retrovir (AZT). Subsequently, the State's AIDS Drug Reimbursement Program low-income criterion was increased and the program gained momentum.

### FUNDING CUT FOR TREATMENT DEMOS

Question. The one area you have proposed to cut in the AIDS budget is a $3.6 million reduction for AIDS service demonstrations and a $6.7 million reduction for the renovation or construction of non-acute care intermediate and long-term care facilities for AIDS patients.

We have heard a great deal about the benefits of these funds. What made you conclude that it should be cut?

Answer. We have proposed sufficient funds in the FY 1989 Budget to add new grantees, continue support of current grantees, provide technical assistance in selected communities, and award grants in high-incidence metropolitan areas not yet served by Service Demonstration Grants.

The FY 1988 funds are being used to increase treatment capacity in high priority areas. Further funds to support the construction and renovation of non-acute facilities for AIDS patients can be obtained through tax-exempt bond financing available through the private sector and, if appropriate, insured by the government.

### AIDS SEROPREVALENCE SURVEYS

Question. Dr. Mason, the Centers for Disease Control (CDC) plans to measure the AIDS infection rates for the general U.S. population. Included within your AIDS budget is $72.9 million for national seroprevalence surveys. Last year we appropriated $10 million for this effort, and were told that the requirement might grow to $17 million. Why are you requesting a $63 million increase, and how will it be used?

Answer. In FY 1988, we are conducting three pilot projects at a cost of $2 million to determine if a national seroprevalence survey could be conducted with any accuracy. If the projects are successful and it is determined to do the national survey, the cost in FY 1989 would be $22.41 million.

Since information about seroprevalence of AIDS is essential to plan for the prevention of AIDS and to evaluate the effectiveness of the AIDS prevention program, it was determined that surveillance in 30 standard metropolitan statistical areas (AMSA) and special ongoing surveillance in selected populations would be required to provide the surveillance information required. Some of these surveillance activities included blinded test and others unblinded.

The 30 SMSAs include testing in STD clinics, TB clinics, drug abuse clinics, women's health clinics, and sentinel hospitals.

The ongoing surveillance include the following populations: military applicants, Job Corps applicants, blood donors, U.S. prisoners, college students, newborn children, cohorts of homosexual men, emergency room personnel, and specimen from private clinics.

The 1989 request of $75.5 million dollars for comprehensive HIV Serologic Seroprevalence includes an increase over 1988 to cover the costs of conducting a National Household Seroprevalence Survey and to continue the sentinel survey in 30 SMSAs. Funds for the Sentinel Surveillance were made available in 1988 by funding cooperative agreements for only a portion of a year in order to avoid the necessity of requesting a supplemental appropriation. The 1989 request will be used as follows:

| | |
|---|---|
| National Household Seroprevalence Survey 1/ | $22,410,000 |
| Special Ongoing Surveillance 2/ | 14,606,250 |
| Sentinel Surveillance (30 SMSA's) 2/ | 38,456,321 |
| Total | $75,472,571 |

1/ One time project - no cost in 1990
2/ Ongoing surveillance

Question. Let me ask you a couple of other questions about the national household study. I understand that you are having difficulty in getting people to participate because they don't want a federal official entering their home, drawing a blood sample, and then testing it for AIDS. I also understand that this is to be a one-time only survey. Is there any scientific evidence that suggests a one-time national household survey would be beneficial?

Answer. We are conducting three pilot projects to determine if people will participate in sufficient numbers to make the results of the survey valid. If they do not, the national survey will not be conducted. The National Household Seroprevalence Survey will be a one time survey to determine the prevalence of HIV infection in the United States. This gives you a one point in time picture of the AIDS problem. That is the reason for the family of surveys, which is an ongoing seroprevalence program to provide information about trends in HIV infection in the general population, as well as, among people potentially at risk.

Question. Couldn't we save the $22.4 million cost of the survey by eliminating it?

Answer. There are a number of questions that must be answered before undertaking the national survey. That is the purpose of the pilot tests that are being funded in FY 88. When the results of the pilot studies are available, an assessment will be made about the feasibility of conducting the survey and whether additional, valuable information will be gained that would justify the expense.

## AIDS FAMILY OF SURVEYS

Question. Returning to the "family" of surveys, I would like to know why it is necessary to study 30 cities. Could you study a smaller number of cities, and still reach valid scientific conclusions about AIDS prevalence in the United States?

Answer. It should be noted that the sentinel surveillance systems established in the 30 cities is a component of the "family" of surveys. In addition, there are special HIV seroprevalence surveys including: military recruit applicants, blood donors, Job Corps applicants, U.S. prisoners, college students, cohorts of homosexual men, NCHS health interview and examination survey respondents, clinical specimens from private physicians' offices, emergency room personnel, and newborn children (through PKU screenings and reflecting maternal infection rates). The thirty standard metropolitan statistical areas (SMSAs) were targeted initially on the basis of cumulative high and moderate to low AIDS incidence rates, reported gonorrhea and syphilis rates, and geographic distribution. All of the SMSAs will not be participating in all of the site and subgroup survey activities (sentinel hospitals, sexually transmitted disease clinics, drug abuse treatment centers, women's health clinics, and tuberculosis control clinics).

Therefore, data from selected sites and subgroups in each of the 30 cities as well as that from the special surveys are necessary to provide sufficient aggregate information on the levels of HIV infection to allow development of prevention strategies.

Question. Secondly, will this "family" of surveys be conducted on an annual basis?

Answer. The "family " of surveys is an ongoing seroprevalence monitoring program to determine HIV infection rates and trends over time in the general public, as well as, various potentially high risk subgroups.

Question. How much funding do you estimate this effort will require on an annual basis?

Answer. It is estimated that $53 million will be required in 1989 to support the "family" of surveys and will approximate that amount on an annual basis. Maintaining our capability to monitor HIV infection rates in the general population and various subgroups is crucial to the development of prevention and control strategies and subsequent evaluation of those efforts.

## AIDS NATIONAL PUBLIC INFORMATION CAMPAIGN

Question. It seems to me that there is still a lot of misinformation about AIDS and the transmission of AIDS. For example, last fall, an employee attitude survey was conducted among 3,000 American workers. The results were disturbing. Two-thirds of the respondents said they would be concerned about using the same bathroom as a person with AIDS on the job, 40 percent were concerned about the same cafeteria, and 37 percent said they would not be willing to use the same equipment as a person with AIDS.

Last year, we appropriated $45.5 million for information and education directed to the general population. Some of that funding was used for the October, 1987 AIDS Awareness Month activities.

What has been our experience with the National Public Information Campaign? Are we getting the message out?

Answer. The National Public Information Campaign was conceptualized during the spring and summer of 1987, and a contract was awarded in August 1987 to the firm of Ogilvy & Mather with the resultant campaign theme "America Responds to AIDS". October 1987 was the kickoff month, and at that time 41 Public Service Announcements (PSA's) for television and radio were distributed, and satellite interviews, 31 discussion forums, 12 leadership meetings, and other activities were conducted. According to our contract with Broadcast Advertisers Report, the PSA's are being used extensively and have resulted in approximately $8 million of free television time. Part of our comprehensive program is the National AIDS Hotline and the National AIDS Clearinghouse. The Hotline number is given as part of each PSA and is listed on all campaign materials and publications.

Following the fall campaign the number of calls to the Hotline increased from 2500 per day to 5500 per day, a volume which has been sustained over time. The Hotline is, at present, responding to approximately 195,000 telephone calls per month, and the Clearinghouse based on publication requests received at the Hotline or direct requests to the Clearinghouse is distributing about 1 million brochures per week. Over 25 million copies of the brochure, "What You Should Know About AIDS", which was developed as part of the October effort, have been distributed.

Question. What national public campaigns are you planning for the next several months?

Answer. The major activity since the fall campaign has been the development of the National AIDS Mailer "Understanding AIDS" required by P.L. 100-202 and the widespread public relations associated with it (advance copies to 1 million health professionals; to State and local health officials; and to media and national, regional, and local organizations). Three waves of activity were planned to follow the fall campaign: Women at Risk (late spring/early summer 1988), Sexually Active Adults (summer/fall 1988), and Parents and Teens (late fall 1988). The recent strike of American Federation of Television and Radio Artists and the Screen Actors Guild has briefly delayed the Women at Risk wave.

Question. Will you be using any methods to measure whether or not these public information campaigns are successful?

Answer. The campaign waves are evaluated in terms of media item usage (television and radio PSA's, printed materials in magazines, press coverage, etc.) through monthly Broadcast Advertisers Reports, matte clipping service reports, and calls to the Hotline. Overall the campaign can be judged to be a success, although direct attribution of changes in knowledge, attitudes, and beliefs directly to the campaign waves is difficult because there is so much going on by both the private and public sectors, that attribution of impact to any one activity is virtually impossible. It can be stated without question, however, that the public's knowledge, attitudes, and beliefs about AIDS and those infected with HIV are improving, and we believe strongly that our efforts have played a major role in this positive change.

## AIDS AND THE MINORITY POPULATION

Question. Minority populations are disproportionately affected by the AIDS epidemic. Statistically, one Black dies in the United States of AIDS every two hours, most often in poverty. Though they make up just 17 percent of the population, Blacks and Hispanics account for 39 percent of the Nation's AIDS cases. More than 70 percent of the women and children who get the disease are from minority groups.

Dr. Mason, the fiscal year 1989 budget request includes $25,156,000 for special minority initiatives. This is an increase of $4,356,000, or 21 percent over last year's effort. How are we targeting our efforts to the special needs of these populations?

Answer. Funds targeted to minorities are available to State and local health departments through the AIDS Prevention and Surveillance Projects cooperative agreements. In fiscal year 1987 CDC awarded more than $7 million to 41 State and local health departments to support community-based initiatives to prevent AIDS among minorities at risk for HIV infection.

Additional funds exceeding $10 million have been awarded to 52 State and local health departments in fiscal year 1988, and CDC will carefully monitor all cooperative agreements to ensure that funds are appropriately distributed to organizations serving communities.

CDC has awarded funds to six community-based demonstration projects in the following areas: Dallas, Texas; Seattle, Washington; Denver, Colorado; Albany, New York; Long Beach, California and Chicago, Illinois. The major focus of these projects is the hard-to-reach groups such as intravenous drug abusers, prostitutes, and street youths. Two of these projects, funded in the amount of $1.3 million through the Chicago Department of Health and the Long Beach Department of Public Health, include specific components which target minorities. Additional funds will be available in 1988.

CDC currently funds three demonstration projects for the prevention of perinatal AIDS. These projects are in Nassau County, New York, New Jersey (Patterson, Jersey City, and Newark), and Houston, Texas. These projects will seek to identify seropositive women and seronegative or untested women many of whom are minorities and are at high risk of acquiring HIV infection. Following this, various interventions will be applied and their effectiveness will be documented and evaluated for application in other areas. It is anticipated that an additional eight projects may be funded in fiscal year 1988.

CDC will have available $8 million in fiscal year 1988 for national activities including grants to national minority organizations to assist in developing special approaches to minority populations, expanded public information efforts directed towards minorities, and a national conference on preventing AIDS among minorities. It is anticipated that funds will be awarded to national minority organizations in late July. Pre-application meetings were held in Los Angeles, Chicago, and Washington, D.C. Post award technical assistance will be provided by CDC.

In September 1987, CDC awarded cooperative agreements to 15 national organizations to help schools and other agencies serving youth provide effective education about AIDS. Of the 15 national organizations funded, five are specifically targeting their efforts toward black and Hispanic youth.

CDC will continue to provide funding to the U.S. Conference of Mayors (USCM) through a cooperative agreement to support an AIDS information/education program targeted for local officials and minority communities. In fiscal year 1987 $580,000 of the $779,233 awarded to USCM went directly to community-based organizations.

Question. Are we coordinating these efforts with the Office of Minority Health?

Answer. CDC continues to coordinate its efforts directed to minority populations with the Office of Minority Health (OMH). OMH participates in the development of AIDS funding guidelines and has representation on the cooperative agreement application review panels.

Question. Do you think there are any problem areas in the minority populations that we are not currently addressing through our AIDS funding?

Answer. During the course of planning another AIDS minority conference, a group of consultants convened by CDC stressed a need to provide training to minority organizations, particularly at the local level, to enhance their effectiveness in contributing to the AIDS prevention effort. Building the capacity of local minority organizations to effectively plan, organize, evaluate and fund their activities will be a key factor in preventing AIDS among minorities. CDC's National Minority Emphasis may, in part, address this need by providing grants to national minority organizations to assist in developing special approaches to minority populations.

## SCHOOL-AGED POPULATION

Question. One of the most potentially vulnerable populations that we need to reach through education and information efforts is the school-aged population. Unfortunately, these young people share a sense of immortality - that something like contracting AIDS will not happen to them.

Dr. Mason, the budget request includes $26.2 million for State and local Departments of Education. How are we reaching these young people through these programs?

Answer. In fiscal year 1987, with approximately $11 million, CDC launched an initiative to help schools across the Nation implement effective school health education to prevent the spread of AIDS. This initiative includes several strategies.

First, CDC has provided funds and technical assistance to 15 national organizations to help schools and other agencies serving youth implement AIDS education programs. Examples of national organizations funded are the National Parents Teachers Association, the National School Boards Association, and the American Association of School Administrators.

CDC has also provided funding and technical assistance to 15 State and 12 city departments of education serving jurisdictions with the highest cumulative incidence of AIDS. These education departments are helping to implement effective AIDS education programs for young people within their jurisdictions. With almost $30 million in fiscal year 1988, CDC hopes to provide funds and technical assistance to the remaining 40 State and Territorial departments of education, approximately four additional city departments of education, and approximately seven additional national organizations.

Additional funding was also provided to 2 of the funded State and 1 of the funded local education agencies to establish AIDS education training and demonstration centers. These centers will train approximately 400-500 personnel from across the Nation each year on how to implement effective AIDS education within their own jurisdictions.

CDC is also helping to develop and disseminate a wide range of educational resources that are appropriate for school and college-aged populations, including curricula, school programs, out-of-school programs, films and videotapes, filmstrips, audiotapes, teacher training programs, books, journal articles, and parent materials. CDC published Guidelines for Education and Foster Care of Children with HIV in 1985, and Guidelines for Effective School Health Education to Prevent the Spread of AIDS in 1988.

Finally, CDC is integrating evaluation research with program efforts to assess the impact of these various activities, and consequently to improve them.

## AIDS EDUCATION REQUIRED IN SCHOOLS

Question. For example, how many States require AIDS education in the schools?

Answer. A survey done by the National Association of State Boards of Education (NASBE) in April 1988, found that twenty States and the District of Columbia require that AIDS education be taught in the schools. These States include: Alabama, Delaware, Georgia, Hawaii, Illinois, Iowa, Kansas, Maryland, Michigan, Nevada, New Mexico, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Virginia, and Washington. NASBE also found that some States, such as West Virginia, do not have AIDS-specific mandates because AIDS is considered a sexually-transmitted disease and instruction about sexually-transmitted diseases is mandated. Oregon and Minnesota are both working toward the mandatory teaching of AIDS in schools.

Question. How does that compare with a year ago?

Answer. Only five States required AIDS education to be taught in schools prior to June 1987.

## AIDS EDUCATION FOR TEENAGERS OUT OF SCHOOL

Question. How about school-aged teenagers, who are currently not in school - are we reaching them?

Answer. No data are currently available regarding the availability of AIDS education to youth who are currently not in school. Plans are underway to assess AIDS-related knowledge, attitudes, and practices among selected out-of-school youth populations.

Currently, all of the 15 State and 12 local education agencies funded by CDC during fiscal year 1987 and all State education agencies that will be funded in fiscal year 1988 are helping or will help to provide AIDS education for school-aged populations that do not attend school. Funded agencies work with juvenile justice and correction agencies, children and youth service agencies, community substance abuse programs, and migrant health programs to help train youth workers, develop and/or disseminate AIDS education materials, and plan AIDS specific programs for out-of-school youth.

Additionally, four national organizations receive cooperative agreement funding from CDC to specifically target their efforts toward out-of-school and minority youth:

- The National Network of Runaway and Youth Services is working with the 290 Federally-funded runaway and homeless youth programs, three national runaway hotlines, and other youth-serving agencies to provide AIDS education for out-of-school youth.
- The National Coalition of Advocates for Students is funded to provide AIDS education for migrant youth, immigrant youth, and disadvantaged youth living in the "blackbelt" counties of the Southeast.
- The Coalition of Hispanic Health and Human Services Organizations is funded to address the specific needs of Hispanic youth as well as the needs of out-of-school youth.
- The National Organization of Black County Officials is funded to address the specific needs of black youth as well as the needs of out-of-school youth.

In FY 1988, CDC anticipates funding a national organization which represents health care providers serving the needs and interests of youth who are in correctional institutions.

## COORDINATION WITH DEPARTMENT OF EDUCATION

Question. Are you coordinating any of these programs with the Department of Education?

Answer. Representatives of the Department of Education have been involved in a number of major programmatic activities conducted by CDC. These include the following:

- Development of Guidelines for Effective School Health Education to Prevent the Spread of AIDS which was published in January 1988.
- Participation on the review panel convened in August, 1987 to assess the quality of cooperative agreement proposals from national organizations and State and local education agencies on School Health Education to Prevent the Spread of AIDS.

- o Participation in the national conference on School Health Education to Prevent the Spread of AIDS held in Washington D.C. in February 1988. Participants included representatives from State and local education agencies as well as national organizations.

- o Participation on an expert review panel, convened by CDC, for integrating AIDS information into two comprehensive school health education curriculum packages: Growing Healthy and Teenage Health Teaching Modules.

CDC looks forward to continuing collaboration with the Department of Education on major programmatic activities.

## AIDS DEMENTIA

Question. At a hearing I held in Miami last August on AIDS, witnesses testified that often the first symptom of AIDS in their patients was dementia. I understand that some airlines and other industries with high-performance jobs are considering AIDS screening for their employees, fearing that their mental abilities might be impaired even though they don't have any visible symptoms of AIDS.

But a group of experts recently convened by the World Health Organization expressed doubts that mental impairment was likely to appear before other AIDS symptoms.

What is the scientific community's latest judgment about dementia as a common first symptom of AIDS?

Answer. At the present time, there is little scientific information about the functional consequences of cognitive impairment observed in a portion of otherwise asymptomatic seropositive individuals. Although cognitive changes have been observed in some individuals, we are not yet confident in predicting if an how those changes affect performance. It is also unclear, at present, what percentage of asymptomatic seropositive individuals experience central nervous system (CNS) effects of HIV infection. There are insufficient data to conclude the extent to which dementia is a common first symptom of AIDS.

Since additional study is needed in this area, NIMH will soon be releasing a program announcement in collaboration with NINCDS on "Central Nervous System Effects of Human Immunodeficiency Virus Infection: Neurobiological and Behavioral Studies." This announcement is designed to encourage studies on the incidence, prevalence, and natural history of neuropsychiatric manifestations of HIV infection, as well as research on the assessment and treatment of cognitive impairment and behavioral dysfunction caused by HIV infection.

Question. Does the evidence available to date suggest that the airlines are being premature if they plan to do AIDS screening to guard against mental impairment among their employees?

Answer. Cases of disabling cognitive impairment have been described int he clinical literature. The potential portion of seropositive individuals who will develop disabling cognitive impairment prior to other signs of HIV infection appears to be small, while a relatively larger number will develop impairment later in the course of illness. Current data are inconsistent regarding the extent of early impairment due to HIV infection. At present, with respect to seropositive individuals who are otherwise asymptomatic, the existing data are insufficient to support policies restricting employment solely on the basis of serostatus.

General screening of individuals for HIV infection would not enable identification of those infected individuals who will develop cognitive impairment. Changes in cognitive function can be identified through behavioral testing; assessment of specific skills may be useful to identify impaired performance.

### AIDS - HEALTH SERVICES RESEARCH

Question. As you know, the Public Health Service has projected that the direct cost of care for AIDS patients in 1991 will be $8 to $16 billion. In addition, the average hospital cost for AIDS treatment ranges from $50,000 to $150,000 per patient.

Yet, up to now, Federal funding for AIDS has focused primarily on biomedical research and prevention programs. Little has been spent on health services research — that is, looking at the cost, financing, and cost-effectiveness of health services for AIDS patients.

Last year, of the $926 million in AIDS funding, $1 million was set aside for studies addressing the direct costs of caring for AIDS patients.

Dr. Windom, the 1989 budget includes $9 million for AIDS health services research. How will that research help our very immediate problem of caring for the projected number of 90,000 persons with AIDS in 1991?

Answer. In FY 1988, NCHSR funded the development of research protocols to be implemented in FY 1989 on the following topics: 1) total direct costs of medical and support services; 2) cost-effectiveness of various treatment modalities; 3) cost-effectiveness of various approaches to the delivery of care; 4) cost comparisons of treating AIDS at varying stages of the disease progression; 5) cost-effectiveness of testing for AIDS under varying assumptions of incidence and prevalence; and 6) costs of training health professionals caring for AIDS cases. It is anticipated that these cost-effective analyses will allow for maximum efficiency in the delivery of high quality, appropriate health services to AIDS patients.

## AIDS 24 HOUR HOTLINE

Question. A 24-hour AIDS hotline has been in operation since 1987.

Will you tell us what happens when you dial the toll-free number? Are you referred to someone for additional information?

Answer. When one dials the Hotline number 1-800-342-AIDS, one receives a taped message on AIDS and the telephone number for an operator who can provide additional information. When one calls the operator, responses to questions are given and requests for publications are recorded. This system is currently being converted to a "call prompt" system so that the caller does not have to redial in order to speak with an operator.

Question. What volume of calls does the hotline handle? Has the volume of calls increased over time?

Answer. The Hotline responds to about 126,000 taped and approximately 69,000 operated assisted calls per month, and the total call volume per day has increased from 2500 prior to the fall campaign to 5500 to 6000 currently.

## AIDS CLEARINGHOUSE

Question. An AIDS clearinghouse has been funded since 1987. What types of information requests does the clearinghouse handle? What is the volume of information requests? How does this compare with other public information? How does someone find out how to obtain information from the clearinghouse?

Answer. The National AIDS Information Clearinghouse was created through a competitively awarded contract in September, 1987. Immediately after the award, in November, the publication distribution services were initiated. Originally there were about 10 titles, currently 18 different PHS approved items are distributed at the rate of about 1 million copies per week.

The Clearinghouse has developed two databases of organizations and educational materials which are available throughout the United States. These databases will continue to be developed throughout the contract, and will serve as the central resource file for all of the programs involved in AIDS information and education activities. Reference specialists began using these databases to respond to inquires from AIDS program managers and other public health professionals in April, and will offer these services throughout the life of the contract. These reference support services are available to everyone, but are designed for assistance in the development and management of programs.

The Clearinghouse has implemented or is developing other program features, such as linkage with the National AIDS Hotline, plans for a bulletin board, and technical support to State AIDS Programs in local program development. From the award of the contract through April 15, 1988, the Clearinghouse has distributed over 22 million general information brochures to the public. Although we do not have precise distribution data for other public health information systems, at the current rate the National AIDS Clearinghouse will distribute more than 3 times the number of materials ordinarily distributed by the National Cancer Institute on an annual basis.

Individuals may learn how to obtain information from the Clearinghouse through the Hotline as well as State and local health departments. In addition, plans are being developed now to more widely publicize the Clearinghouse's services. For example, the National AIDS Mailer "Understanding AIDS" which is going to 107 million households bears the P.O. BOX for the Clearinghouse in the return address — P.O. Box 6003, Rockville, Maryland 20850.

## AIDS - FACILITIES RENOVATION FUNDING

Question. Last year, this Committee heard from several sources that AIDS patient treatment is more cost-effective in an out-patient setting, and that the quality of care is typically better.

Realizing that there is a lack of non-acute care facilities to handle AIDS patients, this Committee provided $6,702,000 for outpatient facility renovation or construction grants.

Have you made the grant awards? Do you have any estimate of the number of applications that you might receive?

Answer. The Health Resources and Services Administration anticipates that the grants for the construction and renovation of non-acute intermediate and long-term care facilities will be awarded in the 4th quarter of FY 1988.

Question. In the fiscal year 1989 $1.3 billion request for AIDS, there is no funding for renovation of facilities. Would you please comment.

Answer. In FY 1988, $6,702,000 was provided for the renovation or construction of non-acute care intermediate and long term care facilities for AIDS patients. In FY 1989 no funds are requested for this activity as resources are being targeted to activities with immediate preventive benefits. Funding support for the renovation and construction of hospitals and non-acute facilities are available on an ongoing basis through the Department of Housing and Urban Development's Section 242 and Section 232 loan insurance programs and through private Tax-exempt bands.

## AIDS - TRAINING FOR HEALTH CARE WORKERS

Question. Funds have been provided to train health care professionals through regional education and training centers. These centers are also supposed to provide a support system through hotlines, clearinghouses, or referral systems.

Have these hotlines been established? Will they tie into the Centers for Disease Control (CDC) main AIDS hotline number?

Answer. Each of the original four Education and Training Centers (ETCs) funded on September 1, 1987 have established their hotlines. However, because the ETC hotlines are designed to serve health care providers while the CDC hotlines serve the general public, the Health Resources and Services Administration has not required that ETC hotlines tie into those at the CDC.

Question. The FY 1989 budget request makes a distinction in grant programs between funding for health professionals through the education/training centers and funding for health professionals employed by community and migrant health centers.

Briefly, what is the difference between the two grant programs? Why can't these groups of health care workers be trained through one grant program?

Answer. The ETCs are designed to provide AIDS training for health care personnel serving the general needs of communities in their respective areas. They also train selected health professionals to serve as instructors for other personnel.

The training of health care personnel staffing community health centers and migrant health centers would focus on their specialized AIDS training need because they serve populations that are primarily medically underserved and contain large numbers of minorities. These populations have disproportionately high numbers of HIV-infected persons whose need for AIDS-related care requires a more immediate response from health professionals.

## AIDS BLOCK GRANTS

Question. During the formulation of the fiscal year 1989 budget, I heard that the Administration considered block-granting some of the AIDS funding, particularly the information and education grant programs. Will you tell us the advantages and disadvantages of the block-grant approach, and why the Administration decided to keep the current structure in place?

Answer. As the funding for AIDS has grown rapidly over the past few years, the PHS has been responding to requests from States and State health departments that Federal AIDS funding for the many separate AIDS information, education, and prevention programs be streamlined.

The advantage of a block grant-type approach is that it would empower the States to take charge of their AIDS problem and would allow them to shift resources to meet their unique needs. The disadvantage is that the Federal government loses its involvement in working with the States to assure that certain problems are addressed.

In 1988, the Centers for Disease Control will consolidate most of their AIDS funding to State health departments into a single AIDS Prevention and Surveillance Cooperative Agreement. This action responds to States' requests for streamlining AIDS funding and still allows the Federal government to work with States to address problems of national significance.

Question. Dr. Mason, the Centers for Disease Control has seen a dramatic increase in program dollars for AIDS-related activities totaled $136,249,000, and now, in fiscal year 1989, the request is $400,719,000, which is about a 200 percent increase in funding.

However, your staffing requests have not shown any similar increase. In fact, while your dollar request increases 31 percent over last year, your staffing request increases 4 percent, from 416 positions to 432 positions.

Given the explosive growth in your AIDS program responsibilities, do you think your staffing level is adequate?

Answer. The staffing levels have not kept up with the increased CDC responsibilities.

Question. What was your staffing request to the Office of Management and Budget (OMB)?

Answer. The HHS request to OMB was 35, excluding the 57 required for the Family of Surveys.

Question. As you know, this Committee has directed that staffing be increased at all of the Public Health Service agencies. What will it take for this to happen?

Answer. The Office of Management and Budget (OMB) has the ultimate responsibility for establishing full time equivalent (FTE) ceilings for the Executive Branch of the Federal government. The only PHS agency that has a special exemption from having FTE ceilings imposed is the Indian Health Service, for which the Congress has elected to grant statutory exemption. To have this same exemption granted to the other PHS agencies would require legislative authority similar to the bill language provided by the Senate in the FY 1988 appropriations bill, but eventually deleted by the Conference Committee.

## AIDS BUDGET REQUEST

Question. As we discussed earlier, Dr. Mason, the amount of resources devoted to AIDS activities has increased dramatically from $136.2 million in fiscal year 1987 to $400.7 million in the fiscal year 1989 request, an increase of almost 200 percent.

How did you arrive at the $400 million request level? What was your request to OMB?

Answer. While it is correct that CDC's AIDS budget increased almost 200 percent from fiscal year 1987 to fiscal year 1989, most of that increase (124 percent) occurred in fiscal year 1988 when Congress appropriated $304,942,000. Substantial increases were authorized particularly for HIV counseling and testing, minority activities, perinatal AIDS prevention and activities directed toward school and college aged youth.

In order to cover related costs associated with the AIDS National Mailer and the comprehensive HIV surveillance system without requesting a supplemental appropriation, CDC funded the fiscal year 1988 AIDS Prevention and Surveillance Projects cooperative agreements for an 8 month period. Most of the increase requested for fiscal year 1989 will be necessary to annualize those cooperative agreements and conduct a National Household Seroprevalence Survey. In addition, $6 million was requested to establish new demonstration projects to determine optimum approaches to preventing and controlling tuberculosis among persons with HIV infection.

CDC's request to OMB for fiscal year 1989 was $296,852.

Question. Do you think this money is carefully spent? Or, do you think too much funding is being distributed too quickly, without careful oversight and monitoring?

Answer. CDC places a high priority on ensuring that AIDS funds are expended in accordance with specific written plans. For example, approximately 44 percent of CDC's fiscal year 1988 AIDS budget will be awarded to State and local departments of health and/or education only after submission and objective review of comprehensive cooperative agreement applications. Final funding awards will be carefully negotiated to maximize potential effectiveness. CDC will then monitor progress and provide technical assistance as necessary to facilitate the accomplishment of program objectives. To assure that our oversight and technical assistance can keep pace with the program expansion additional staff is being hired by each Center that awards funds to States.

## HEALTH SERVICES RESEARCH-FUNDING LEVEL

Question. I think health services research is really useful in streamlining and standardizing our health care delivery in this country. Therefore, Dr. Windom, I am perplexed by your lack of funding in this area. as compared to other health research budgets.

For example, the budget request for the National Institutes of Health, without AIDS funding, reflects a 5.4 percent increase. More dramatic is the 19 percent increase in the research budget for the Health Care Financing Administration (HCFA). As far as I understand, you and HCFA both conduct applied health services research.

However, you are requesting $16.8 million for Fiscal Year 1989, an increase of $196,000, or 1 percent, over last year's appropriation of $16.6 million.

— Dr. Windom, why do the other agencies fare better than you in health research funding increases?

Answer. Although the request for budget authority reflects only a 1 percent increase, NCHSR does receive funding from other sources.

For instance, NCHSR receives 7-1/2 percent of resources allocated for evaluation (Section 2313). These amounts are tied directly to the appropriated levels of the PHS agencies. Therefore, when these amounts are increased, NCHSR's share is increased.

Likewise, NCHSR receives funds for National Research Service Awards. Their share is 1/2 of 1 percent of the amounts available to NIH and ADAMHA for these awards. Again, when those agencies receive funding increases, so does NCHSR.

It should also be noted that the FY 1989 request for AIDS funding for NCHSR is $9 million, an increase of $8 million over the FY 1988 amount.

## ADOLESCENT FAMILY LIFE - NO PHASEOUT FUNDING

Question. The Adolescent Family Life demonstration program funds grants for community-based health care services for pregnant teenagers and teen pregnancy prevention services to reach teens before they become sexually active.

This program has been funded as a demonstration program since fiscal year 1982. The program has been unauthorized since fiscal year 1985, and has been funded under continuing resolutions since that time.

Last year in hearing testimony, your agency stated that a decrease in the funding request represented the first year of a planned three-year phaseout. Congress agreed with the funding cut of $4.5 million, and appropriated $9.6 million. The reasoning was that the seven year old demonstration program had evaluated over 100 tested innovative approaches to health services delivery, and that these models were being disseminated to interested communities.

This year, you are requesting $9.6 million, the same amount as last year's appropriation. There is no second year phasedown in the funding request.

-- Why have you requested level funding for this program?

-- What has changed from your testimony last year to continue the same level of funding? Aren't you going to phase out the program?

Answer. The Department is not planning to phaseout the Adolescent Family Life (AFL) program. Last year's proposal for phaseout was reversed for several reasons. First, the President's Task Force on Adoption strongly supported continuation of the program because of its focus on adoption as a positive alternative to early parenting. The AFL program is the only Federal program focused exclusively on the problems of teenage pregnancy. Also, it became apparent that the program has had some very positive accomplishments; for example, several States have developed and funded their own teen pregnancy programs based on new approaches developed by AFL funded projects.

The requested funding level for FY 1989 will permit continuation support for all grantees until the end of their project periods and will also fund 19 new demonstration and six new research awards.

## FAMILY PLANNING (TITLE X)

Question. Once again, the Administration is proposing to fund the Family Planning Program as a single block grant program to the States. Currently the program is administered as a formula grant program. Although the fiscal year 1989 budget request is essentially level funded at $140 million, the budget justification indicates that there will be a savings of 40 full-time equivalent (FTE) positions, if the proposed block grant is enacted.

Since the block grant proposal would require legislative language, and since this program has been unauthorized since fiscal year 1985, it seems very unlikely that this proposal would be enacted.

-- Given that the family planning program will most likely be administered in its current form, how much additional funding would be required to maintain the 40 staff positions?

Answer. In the event that Congress does not enact the Family Planning State Administered Grant Program, the FY 1989 request for $140 million would support the family planning categorical program and all of the FTE currently required to administer the program.

## PROPOSED BAN ON ABORTION COUNSELING SUSPENDED

Question. Last year, the Administration proposed new rules to ban abortion counseling and referrals at federally funded family planning clinics. In early March of this year, a federal judge in Boston issued a permanent injunction to block the proposed rules. As I understand it, the current regulations will remain in effect until the permanent injunction is lifted.

-- Does the Department have any plans to respond to the permanent injunction?

Answer. On March 3, the judge in the Boston District Court entered a final judgment and a permanent injunction against enforcement of the regulations. The government is appealing that decision and has filed its appeal brief with the First Circuit Court of Appeals. Because it is unclear which organizations are covered by the injunction, the District Court has ordered the plaintiffs to identify their membership in order to clarify which organizations are subject to the injunction.

Pending clarification of the scope of the injunction, family planning regional offices have been instructed not to take action to implement the regulations.

## SCHOOL-BASED HEALTH CLINICS

Question. What role, if any, does the Title X program have in supporting school-based health clinics? Do you think the program should get involved in this area?

Answer. While the Department has no specific policy on the funding of contraceptive services in school-based clinics, the Secretary has expressed concern that the presence of a Federally funded program in which access to contraceptives is enhanced may send a mixed message, especially to younger teens, that being sexually active is sanctioned or expected behavior.

The results of an informal survey among Title X grantees indicate that Title X funds are not being used to provide contraceptives in school based clinics. However, the current Title X legislation, regulations, and guidelines do not prohibit such use of Title X funds.

## ADOPTION

Question. What, if anything, do Title X clinics do in providing information and counseling for adoption placement services? What is your view about the possibility of increasing the clinics' role in adoption placement?

Answer. The issue of adoption information and counseling services in the Title X program may be raised in two contexts-- as a service for the management of infertility or as a service for the management of a pregnancy. In the first instance, services should be offered by the project on site or by referral. The definition of family planning that is incorporated in the new regulations makes clear that adoption services should be offered in the Title X program as a service for the management of infertility. The preamble explains that infertility services and adoption are both approaches which constitute legitimate means of determining family size and spacing and that adoption is simply one means of addressing the broader problem of infertility. In the second case, while provision of adoption services for pregnant women is beyond the scope of the Title X project, the project should provide a referral for adoption services as it would provide for any other appropriate social service.

The Office of Population Affairs (OPA) has undertaken several activities in support of adoption as an option in both the Title X and Title XX programs. OPA has developed and disseminated to Title X grantees both The Adoption Option - A Guidebook for Pregnancy Counselors, a guidebook to assist counselors who work with pregnant teenagers in learning about adoption, and an adoption resource directory. The Clearinghouse also maintains information on adoption which is available to all OPA grantees. In addition, as a condition of grant award, Title X training grantees are required to have an adoption component in their curricula.

## USER LIAISON PROGRAM

Question. This Committee last year urged that NCHSR re-establish the User Liaison Program in the most economically efficient method possible, given current funding constraints. In your FY89 budget justification for OASH, you state that the User Liaison Program "has been re-established and functions effectively as an office within NCHSR." Please describe how it has been changed to operate more efficiently as we urged. What changes have been made in the program?

Answer. First of all, to clarify the situation, the NCHSR User Liaison Program was never eliminated. The use of the word "re-established" in the budget justification was unfortunately misleading.

The size of the program's staff is now smaller than in previous years. However, the program has retained its ability to develop and conduct workshops on major issues in the financing and delivery of health services for senior State and local executives as well as State legislators and others concerned with these issues. Participants continue to rate these workshops highly. The Program has also been able to conduct several series of shorter workshops on key topics for which longer workshops had been given. This stretches the resources invested in initial workshop design and development. For example, following several longer AIDS workshops, the NCHSR User Liaison Program is currently conducting a series of one-day workshops dealing with the impact of AIDS on State governments.

The User Liaison Program has ceased to conduct single state workshops, i.e., workshops in which the audience is from one state and the agenda is designed to fit the particular needs of that state. These single state workshops were well received, but the investment required to develop a new agenda, tailored for specific state needs, was much more costly than the "series" approach mentioned above.

## PATIENT OUTCOMES RESEARCH

Question. When Congress passed the authorization for a patient outcomes program, we specifically assigned the program to the National Center for Health Services Research. Now we see that the program has been shifted to the Health Resources and Services Administration (HRSA).

Would you clear the air for us, Doctor? Why begin a new program in the Health Resources and Services Administration (HRSA) after Congress authorized and appropriated the funds to the National Center?

Answer. The decision was made that in lieu of requesting trust fund money in FY 1989, a request for $15 million would be included in the HRSA budget for the health care improvement fund. If the program is funded from the trust funds, the program is restricted to studies which benefit the Medicare population. Since our desire is to broaden the program, to include the entire population, we are seeking resources under a more general authority.

Question. Whose decision was it to drop the program from NCHSR and shift it to HRSA? Yours or the Office of Management and Budget?

Answer. The Health Care Improvement Fund will be utilized by both NCHSR and HRSA to address a variety of issues. The work of the two agencies will complement each other.

NCHSR will:

- o Evaluate patient outcomes to determine the appropriateness of medical treatments and surgical procedures.
- o Develop and improve databases and research methodologies necessary to evaluate patient outcomes.
- o Work (in conjunction with HRSA, HCFA, NIH and private organizations) to acquire information from which to develop clinical protocols for "quality care" and to develop mechanisms through which to disseminate and encourage adoption of clinically useful information on medical care.

HRSA will:

- o Develop and strengthen professional education and practice improvements.

- o Strengthen public institutions' capacity to protect the public's health through identification of and restrictions on substandard medical care.
- o Measure cost and efficacy of provider's quality assurance/resource management systems; measure decrease in ineffective and inappropriate care; and measure expected decrease in claims rates for such care.

Question. Last year, Congress expressed some concerns that the National Center was in jeopardy of being weakened by reorganizations or transfers. In fact, Congress specifically directed that the Secretary may not alter the administrative relationship between the Assistant Secretary for Health and the Director of the National Center.

In effect, haven't you done just that by moving the patient outcomes program to the Health Resources and Services Administration (HRSA)?

Answer. The administrative relationship between the Assistant Secretary for Health and the Director, NCHSR has not been changed and there are no plans to change it.

## DISEASE PREVENTION AND HEALTH PROMOTION

Question. The Office of Disease Prevention is the principal office within the Department of Health and Human Services for health prevention coordination. The Office oversees implementation of the 1990 prevention objectives, coordinates the Department's efforts in nutrition, disseminates health information, and encourages health promotion through the public and private sectors.

The fiscal year 1989 budget request is $3 million, a reduction of $486,000 or 14 percent, from last year's appropriation. Given the many health promotion and disease prevention activities of this office, why are you proposing this cut?

Answer. In order to concentrate resources on higher priority activities of the Public Health Service, resources for the Office of Disease Prevention and Health Promotion (ODPHP) were reduced.

Question. What activities will be reduced?

Answer. The activities that will be affected are:

- o Cooperative agreement program -- ODPHP will terminate agreements with national membership organizations which support the implementation of national health objectives. The current set of cooperative agreements expire in FY 1988, a new set will not be funded in FY 1989.

- o Nutrition activities — ODPHP will decrease the allocation of resources for nutrition initiatives. The decrease reflects the completion in FY 1988 of the Surgeon General's Report on Nutrition and Health and the scale back of follow-up implementation plans.

NATIONAL PLAN FOR PREVENTION OF DISABILITIES

Question. Two to five percent of school-aged children have major developmental disabilities, such as mental retardation, cerebral palsy, blindness, and hearing impairments. Some of these disabilities could be prevented if known interventions were implemented.

Last year the Congress provided $3.8 million for a developmental disabilities prevention program to be administered through the Centers for Disease Control (CDC). The idea of the program is to build a capacity at the State and local levels to effectively implement prevention measures.

In last year's report, the Committee requested the Office of Disease Prevention and Health Promotion to develop a national plan for the prevention of primary and secondary disabilities.

- — Will your office integrate the Centers for Disease control (CDC)program into your national plan, since the CDC program is administered through the States?
- — What is the status of the national plan? When do you expect to report to Congress?
- — What other strategies will the national plan advocate to prevent disabilities?

Answer. Over the past year, the Office of Disease Prevention and Health Promotion (ODPHP) and the National Council on the Handicapped (NCH) have formed a Federal ad hoc group to coordinate intergovernmental interest in the prevention of disabilities and to support development of a national strategy. Representatives from the Departments of Education and Health and Human Services, together with NCH, regularly attend the bimonthly meetings. HHS agencies participating include the Centers for Disease Control, the Health Resources and Services Administration, the National Institutes of Health, the Administration on Developmental Disabilities the President's Committee on Mental Retardation, the Social Security Administration, and the Office of the Assistant Secretary for Planning and Evaluation. Department of Education agencies participating include the Office of Special Education and Rehabilitation Services, the National Institute on Disability and Rehabilitation Research, and the Rehabilitation Services Administration.

The first charge of the Ad Hoc Group has been to link the development of a national strategy for the prevention of disability to the development of national health promotion and disease prevention objectives for the Year 2000. An initial task has been undertaken by ODPHP to review the 1990 Health Objectives for the Nation for objectives relevant to this effort, identify gaps which should be addressed in the development of a disability prevention strategy, and data sources on the incidence and prevalence of the principal preventable disabilities. This report will become a source document for lead agencies in the Public Health Service responsible for drafting Health Objectives for the year 2000, with instructions that, in addition to the 1990 Objectives' focus on reductions in premature mortality, consideration be given to the prevention of disabilities and secondary and concurrent diseases and disabilities.

The inclusion of disability prevention targets in the year 2000 objectives sets the stage for the development of a national strategy to meet those targets. To document the magnitude and characteristics of the problem, identify needs and opportunities for prevention, and develop criteria for setting research and program priorities, the Centers for Disease Control intends to commission a report on the state of the science in prevention of disabilities. CDC will use the Ad Hoc Group to review plans for and development of the report, expected for release in FY 1989. The report will also be used by CDC to set priorities for funding State disability prevention efforts.

A national plan to prevent disabilities will benefit from the groundwork laid by these efforts in its ability to set priorities, offer effective strategies, and enlist the support of the critical participants from public and private, consumer and provider, national and local, education and health sectors. A final report should follow the release of CDC's study and coincide with the announcement of the year 2000 health objectives in 1990.

## OFFICE OF MINORITY HEALTH

Question. Last year, the Conference committee urged the Public Health Service to develop a coordinated plan to implement the recommendations of the Secretary's Task Force Report on Black and Minority Health. The overall effort was to be coordinated by the Office of Minority Health. The Task Force recommendations included improvements in (1) health information and education, (2) health professions development, (3) research, and (4) delivering and financing health services.

What is the status of the plan? Have specific projects and annual funding goals been established?

Answer. In FY 1987, as the first step in carrying out its mission, the Office of Minority health (OMH) developed and issued guidance to DHHS agencies entitled, "Minority Health: HHS-Wide Program Coordination Process and Goals for the Year 2000", and thereby established the Health Issues Working Groups (HIWGs) as the mechanism through which OMH coordinates the minority health-related activities of the agencies within the Department. Specifically through the use of nine working groups, this process is an effort to (1) examine the gaps and needs in the six diseases and the three problem areas, (access and financing of health care, health data, and manpower issues) identified in the Task Force Report and (2) develop a coordinated strategic plan with measurable short and long range goals and objectives.

Each working group is charged with the responsibility of examining its disease or problem area in detail with a view towards reviewing current program strategies with respect to minorities. The Health Issues Working Groups (HIWGs) will complete a four phase process which is expected to increase the impact of existing programs on minority health. These four phases are:

- Phase I - Systematic Program Assessment
- Phase II - Goal Formation
- Phase III- Development of the Minority Health Strategic Plan; and
- Phase IV - Implementation of the Strategic Plan

Currently, the nine Health Issues Working Groups are completing Phase I-Systematic Program Assessment which consists of four tasks necessary to develop program review of minority health issues in DHHS. These tasks include: (1) an inventory of DHHS programs; (2) consolidation and integration of results; (3) an assessment of baseline data on programs, gaps and overlaps within DHHS; and (4) an evaluation to determine unmet needs in minority health. In response to Congressional request, OMH submitted in "draft" the assessment of the program reviews of the six priority diseases.

Specific projects and annual funding goals will be developed during Phase III - Development of the Minority Health Strategic plan. The plan will identify priorities and strategies for achieving the short-range, medium-range, and long-range goals. Priorities will be based on the severity of the need for improvement of minority health in specific disease or cross-cutting areas where disparities with the majority population are most acute. The Strategic Plan will establish priorities for the objectives and goals within the eight general areas of recommendations of the Secretary's Task Force Report and will discuss broad strategies the Department can pursue for influencing trends and developments in minority health.

## COMMUNITY RISK REDUCTION GRANTS

Question. The Office of Minority Health is responsible for administering the Community Health Risk Reduction Grants. These two-year grant awards are used to support health risk reduction efforts for such health problems as cancer, cardiovascular disease, and obesity.

In fiscal year 1987, $1.2 million was awarded to six grantees for this program. The fiscal year 1989 budget request continues the same level of funding for this program. It is well documented that minority populations experience a higher incidence of preventable diseases that the general population.

Don't you think that this grant program is at best, a minimal effort in addressing the special health needs of the minority population?

Answer. The OMH Minority Community Health Coalition Demonstration Grant Program is but one mechanism for addressing the special health needs of the minority population.

The intent of the coalition demonstration program is to demonstrate the efficacy of health promotion/risk reduction interventions that utilize coalitions of community-based organizations which can then be supported by State, local or private funding. The program is based on the premise that a community-based coalition can be a more effective mechanism for stimulating and reinforcing less risky and healthier behaviors. Conventional health promotion activities are frequently not effective in reaching minority populations. However, it appears, and we hope that the coalition demonstration program will help to show, that the change can be achieved by community-based information dissemination, awareness, support, and exhortation, particularly if such a community health campaign is carried out using familiar institutions and recognized community leaders.

Question. How many applications did you receive for this program last year? In total, how much funding did these potential applicants request?

Answer. In FY 1987, 138 applications were submitted to the OMH Coalition Demonstration Grant Program. The total funds requested by all the applicants, including both approved and unapproved applications, in FY 1987 were over $26 million.

## STAFFING

Question. The Fiscal Year 1989 budget request reduces the management account by 14 full time equivalent (FTE) positions for a savings of $825,000. However, funds for contracting personnel services to conduct "a variety of management analyses" are increased by $780,000. The net program savings in $45,000.

Are the staff positions proposed for elimination equal in qualification to conduct the management analyses? If so, why are you proposing to eliminate the positions?

Answer. The types of analyses that would be conducted by the contractors would be very similar to analyses currently being conducted and would require the same skills and qualifications. We have sought to reduce our FTE's and this is a way of doing that while maintaining essential management analyses functions.

### RURAL HEALTH RESEARCH

Question. In the FY 1986 appropriations bill, this subcommittee provided funds to NCHSR to hold a conference in order to set an agenda and establish funding needs for health research focused on the particular problems of health care delivery to rural America. I would like to put the research agenda and funding projections in the hearing record.

Would you please give the subcommittee a report on the conference, and the rural health agenda?

Answer. The conference was held in December 1987, and administered by the National Rural Health Association and the Foundation for Health Services Financing Administration. The preliminary report and research agenda were received by NCHSR on April 22, 1988. We expect to be able to provide you with the report later this year.

## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### SUGAR INTAKE AND TOOTH DECAY

Question. Over the past decades, the incidences of tooth decay have decreased dramatically, even in light of a per capita increase in the intake of sweeteners. Accordingly, does the control of sugar intake offer a proven means of controlling tooth decay in children?

Answer. The fact that dental health has improved despite continued high consumption of sugar is more a testimonial to the effectiveness of fluorides from various sources than an exoneration of the role of sugar in causing tooth decay. Dental caries results from the interactions of three factors: bacteria, environment, and host. A sufficient population of decay-causing bacteria must be present on the tooth surface. Highly refined carbohydrates, such as sugar (from the environment), must be eaten frequently. The sugar is metabolized by the bacteria to produce the acid which dissolves tooth enamel. Finally, the teeth (host) must be prone to the caries process. Developing teeth are generally more vulnerable to decay than mature teeth.

It is essential to address all three causative factors when trying to prevent tooth decay. Fluoride helps make the tooth caries resistant. A reduction in the frequency of consuming sugars also will reduce the number of decayed teeth. Less frequent between-meal consumption of sugar-containing snacks is very important in this respect. Control of dental caries through the modification of food habits is fraught with problems of compliance in our society. Nevertheless, educational messages that discourage consuming between-meal sweet snacks should continue.

Also, it should be noted that although recent declines in caries demonstrate that significant gains have been made in improving dental health in children, a sizable problem still exists, particularly within certain subgroups of the population. This underscores the need for multiple measures including attention to the frequent consumption of sugar--in order to achieve an optimal level of dental health.

Question. Have any tests been done to determine whether the elimination of sugar snacks from children's diets during school has any affect on their overall health if children's sugar intake is not otherwise restricted?

Answer. There have been two studies conducted in Australia on the effect . of selling sweets in school canteens on the caries increment of school children. Both showed that children had a lower caries increment in schools not selling sweets. Fanning, et al. (1969) recorded a two-year increment of 10.9 decayed, missing or filled tooth surfaces (DMFS) in 981 children attending Adelaide secondary schools where sweets were sold, and 9.3 DMFS in 285 children attending schools not selling sweets; a difference of 1.57 surfaces or 14 percent. Roder (1973) recorded two-year caries increments in younger children attending government and private schools. In half the schools of each type, sweets were not on sale. The 337 five-to-nine-year-old children attending the government schools which did not sell sweets developed 0.9 DMFS, 16 percent less caries than the same number of matched children in the schools which sold sweets. Similarly, 314 seven-to-13-year-old children in private:schools not selling sweets had 2.6 DMFS, 30 percent less caries than matched children in the private schools selling sweets. Furthermore, the frequency with which the children attended the canteens was recorded, and the frequent users of the canteens selling sweets had the highest caries increments.

Question. It is my understanding that Objective "D" seeks to eliminate "highly cariogenic foods" from the school lunch program and vending machines located on school grounds, What comparable efforts will be undertaken to protect the child from the refrigerator at home, the street corner candy store or fast-food chain outlets, which offer a wide variety of nutritionally deficient products, many of which have no relationship to a balanced intake of sugar in the diet?

Answer. In discussion of Objective D, The 1990 Health Objectives for the Nation: A Midcourse Review also stated: "A number of factors operate to impede achievement of this objective. Sugared snacks have become very widespread in schools and public and private health facilities. The U.S. Department of Agriculture recently determined that the presence of a federally supported school food program within a school does not provide authority to bar the sale of snack foods on the school premises except during specified meal times. . . . It would be preferable for the objective to call for alternative snack items (properly identified) to be available to children in school. This would allow for a health education message, promote the substitution of safer foods for clearly highly cariogenic foods, and not undermine the generation of revenue for the schools."

In recent years Americans as a whole have become keenly aware of the role of nutrition in promoting and maintaining good health. Food service industries have developed an increasingly wide selection of more healthful foods. Food labeling, including sugar content, has enabled consumers to make more intelligent choices. Public education programs sponsored by hospitals, private industry, and schools at every level, and local, state and Federal governments, continue to emphasize the importance of good nutritional choices, including limiting sugar and sugary food consumption for both children and adults.

Question. In view of the horrendous drug problem in American schools, is it reasonable to focus on the elimination of sugar from school lunches when the problem of drug intake into a child's body is far more heinous and deadly?

Answer. The problem of drugs and school children is a very real one that . requires our best efforts to eradicate. While the nation works to resolve this problem, however, we cannot ignore the multifaceted needs of the developing child. Many years of scientific research have confirmed that lowering sugar consumption is directly linked to reducing dental caries in children. There is a growing awareness of obesity in children that is similarly linked to diet. We would be remiss if we were to ignore protecting our children from the problems associated with overconsumption of sugar and/or fat while addressing other valid concerns about the quality of life.

## SUGAR CONSUMPTION AND HEALTH

Question. The federal government has accorded sugar "GRAS" (generally recognized as safe) status. What current information do you have which concludes that sugar consumption has any hazardous "direct cause and effect" relationship with human health?

Answer. Recent reviews of extensive animal studies and human epidemiological and clinical observations over the past 30 years have thoroughly documented the role of sucrose and other sugars in tooth decay. Following are some examples:

A high incidence of early#aries lesions was produced in only 21 days in six students who rinsed their mouths nine times a day with 10 ml of a 50 percent sucrose solution (von der Fehr, et al., 1970). Similar findings were reported by Geddes, et al. (1978).

Anais (1978) showed that the mean number of decayed, missing, or filled tooth surfaces (DMFT) for 722 workers in the sweets industry was 15.6. This compared to a mean DMFT of 9.1 for a control group of 812 workers in the textile industry. He further showed that the DMF rate increased significantly in relation to the duration of employment in the candy factories.

Humans with the rare disease hereditary fructose intolerance are unable to metabolize fructose. Because fructose is a component of sucrose, they severely restrict their intake of ordinary table sugar. It has been observed that these individuals have little or no caries (Marthaler, 1967; Newbrun, et al., 1980).

Question. What attempts are being made to ensure that the recognized nutrition experts and nutritional research centers are given the opportunity to provide accurate, reliable and beneficial health information to the general populace, including school children, which will help debunk erroneous information associated with the intake of sugar and, at the same time, educate the public as to their necessity of a proper balance of sugar in the diet?

Answer. We are uncertain concerning the nature of "erroneous information associated with the intake of sugar." Sugars and other carbohydrates occur naturally in foods which make up a well-balanced diet. Dental research has documented the risk of tooth decay associated with diets high in sugar and the frequent consumption of sugar-containing snacks. We know of no professionally reputable nutrition research center or sugar.

## QUESTION SUBMITTED BY SENATOR DALE BUMPERS

### AIDS VACCINE

Question. Describe for us the success and problems you are having in developing and testing a vaccine for AIDS?

Answer. The first AIDS vaccine trials have already begun. These first tests are called Phase I, and are testing the safety and immunogenicity of experimental AIDS vaccines in small numbers of volunteers. The first product to be tested is known as gp 160, which is a protein of the AIDS virus engineered by recombinant DNA technology. This product is being tested both at the NIH Clinical Center and at the NIAID Vaccine Evaluation Units. The preliminary data that we have from these studies indicates that the product has not produced any significant adverse reactions, and induces antibodies directed against the gp 160. The volunteers in these trials are healthy adults, who are HIV seronegative and not at high risk for HIV infection. We anticipate that other experimental AIDS vaccines will be tested at the Vaccine Evaluation Units in the near future.

Vaccine development efforts are proceeding rapidly, with industry, academia, and government scientists collaborating on a variety of approaches to AIDS vaccines. As the agency of the PHS with the lead responsibility for AIDS vaccine development and evaluation, the NIH generated an AIDS Vaccine Plan to create a framework for insuring that all steps in the vaccine development process will be addressed, and that vaccine development will only be limited by the rate of scientific progress in basic research. The major points of the plan are that it:

- o provides for a comprehensive strategy for AIDS vaccine development
- o minimizes disincentives to vaccine innovation and production
- o utilizes innovative approaches to foster collaboration between government, industry, and academic scientists
- o provides for a network of national resources to facilitate AIDS vaccine development
- o provides for a coordinated and flexible system to review and set priorities for resource allocation
- o provides for technology transfer. reagent production and standardization. and information exchange

Although formidable challenges still remain on the path towards a safe and effective AIDS vaccine, progress in understanding the immune response against this virus continues to provide scientists with clues toward designing a successful vaccine.

## QUESTIONS SUBMITTED BY SENATOR FRANK LAUTENBERG

### AIDS

Question. New Jersey has the fourth largest number of AIDS cases in the nation behind California, New York and Florida. Last year only four cities in the nation became eligible for the Service Demonstration Project grants to assist in providing AIDS treatment and prevention services. Given potential increases in the Public Health Service budget for AIDS, what is the Department doing to ensure that federal resources are targeted to those States with the greatest number of AIDS cases, and the highest rate of increase of the disease?

Answer. By the end of FY 1987, 13 AIDS Service Demonstration Centers had been established. A total of 20 should be in operation by the end of FY 1988. As many as 25 centers could be operational by the end of FY 1989. In awarding its Service Demonstration Grants, the Health Resources and Services Administration has given preference to SMSAs with high numbers of AIDS cases. Currently, one of our grantees is Newark, New Jersey. For the FY 1988 grant cycle which was announced in the Federal Register on April 14, Jersey City and Burlington County outside of Philadelphia are listed in the notice as eligible applicants. Consideration is also given to an applicant's ability to form the coalitions of community organizations necessary to demonstrate the efficient and effective provision of AIDS services.

Question. Many AIDS patients can benefit from home and community based care rather than hospitalization. There are a great many of victims of this disease who have no access to care in their homes or communities. The Senate Labor and Human Resources Committee's report on S. 1220, the AIDS Research and

Information Act of 1987, stated that "there is a great need for the increased availability of home and community based services in order to provide appropriate care for people with AIDS." The Senate Labor and Human Resources Committee recognized the need to increase training for health care professionals for infection control and treatment of AIDS patients. What policies are currently underway or planned by the Department to expand the availability of home and community-based health services for AIDS patients? What guidance or assistance will the Department provide to encourage States to increase their role in providing home and community based services? Does the Department plan to make funds available to study community-based care for AIDS patients?

Answer. One of the primary goals of the Service Demonstration Grants program of the Health Resources and Services Administration (HRSA) is to show how collaboration among a community's acute and non-acute health care providers results in more efficient delivery of AIDS services. The non-acute services stressed under this program includes those provided in domiciliary, intermediate, and hospice settings.

In the fourth quarter of FY 1988, it is anticipated that the HRSA will award a total of $6.7 million in construction and renovation grants. These grants are designed to increase capacity of non-acute intermediate and long term care facilities that provide comprehensive cost effective care to HIV-infected persons.

Under the Medicaid program, States can establish coverage by choosing from a list of optional services that include hospice benefits, inpatient or residential care, and case management services targeted to specific groups. States may also be eligible for specific home and community-based services waivers.

States and metropolitan areas will be encouraged to increase their role in providing home and community-based services through the Service Demonstration Grant program.

Question. There is a great demand to increase training of health professionals to care for AIDS patients. Clearly, the nursing profession will play a larger role in the care of AIDS patients. At the same time that the demand for professionals knowledgeable about AIDS is increasing, the nation is suffering from a serious nursing shortage. The Department is providing funds to establish AIDS education and training centers for health care workers. What is the Agency's view on making grants available to groups of health professionals and States to conduct their own training on the care of AIDS patients?

Answer. The approach taken by the HRSA in awarding grants for AIDS Education and Training Centers is to establish regional centers which, in turn, collaborate with State and local health departments, health professions schools, and other providers. This approach enables large numbers of organizations responsible for both direct patient care and the training of additional health professionals to benefit from the limited number of health care professionals knowledgeable in the care and treatment of AIDS patients.

Question. What plans, if any, does the Department have to expand resources for the treatment and the prevention of pediatric AIDS? How does the Department intend to involve hospitals in this process? How will resources be targeted toward the States with the highest rate of pediatric AIDS cases?

Answer. The Department plans to expand resources for the treatment and the prevention of pediatric AIDS by developing collaborative and cooperative efforts among all public and privately supported health service and related programs in any given community. This is being accomplished through the pediatric health care demonstration program. Hospitals are an integral component of the pediatric health care demonstration projects, primarily as providers of ambulatory care. To date, applications for funds under the new pediatric health care demonstration program have not been received from those States with the highest incidence of pediatric AIDS.

Most applications for the new FY 1988 Pediatric AIDS Health Care Demonstration Grants is are being submitted from the geographic areas with the greatest number of infants and children with HIV infection and AIDS. The Maternal and Child Health program has been working closely with these communities to encourage joint planning at the community level and collaboration and coordination with all other AIDS related programs in the community. The PROGRAM GUIDE for Applicants states this and it has been emphasized in all the technical assistance efforts, including two Workshops where community groups were brought together.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### CONSOLIDATED AIDS ACCOUNT

Question. Dr. Windom, last year Congress chose not to consolidate all AIDS funding in one account and, instead, appropriated the funds to individual agencies by individual line items.

Why has the Department proposed consolidating all the FY 1989 funds under your Office as Assistant Secretary for Health?

Answer. There are several reasons for requesting all AIDS resources in a single account.

The single account concept will provide for a greater degree of flexibility to meet changing requirements. AIDS research is dynamic making it difficult to predict exactly where science will be several years in advance, as required by the budget process. We believe that the consolidated account concept will allow PHS to reallocate resources to meet emerging needs with greater ease.

Consolidation of AIDS funding will allow greater coordination across the agencies of PHS. For example, currently at the National Institutes of Health, sixteen components are involved in different aspects of AIDS research and prevention are pursued, to foster better interagency communication, and to avoid unnecessary duplication.

Centralization of resources will promote the degree of visibility in the budget process that is commensurate with the high priority placed on the AIDS epidemic by the Administration.

Question. Isn't sufficient coordination provided by the AIDS Coordinator and all of the interagency committees that have been created over the last few years? Wouldn't you agree that such a consolidation would threaten to slow down a process that many of us have been trying to expedite?

Answer. While the coordination of the PHS AIDS effort has been excellent, we believe that the consolidation of the AIDS account would afford PHS a better system for coordinating and allocating AIDS resources.

Our AIDS request proposes having a contingency of $15 million to be withheld from initial allocation. This contingency fund allows PHS additional flexibility and would afford PHS a funding mechanism to provide immediate allocation of resources in response to any urgent request for additional AIDS resources.

Additionally, we are proposing a general provision that would allow the transfer of up to 3 percent from any PHS appropriation (except Retired Pay) to the AIDS account. The purpose of our proposal which is to increase our flexibility to manage the total AIDS effort and to be more responsive to changing priorities resulting from new opportunities including scientific breakthroughs in AIDS research and prevention. Current reprogramming rules and procedures for shifting (non-AIDS) resources within an appropriation are very restrictive and require considerable time. We believe that our proposal would serve to expedite the process of allocation of AIDS resources.

Question. How much did you request from the NIH budget office for AIDS research in your Institute for FY 1989?

Answer. NIAID submitted a preliminary budget request to NIH for $394,945,000 for AIDS research in FY 1989.

Question. In your professional judgment, is the $310,268,000 requested in the President's budget enough to meet the research needs of FY 1989?

Answer. Because of the very special nature of the AIDS effort --because it changes so rapidly--we are constantly reassessing our needs and with that reassessment we will be able to answer this question more accurately.

## NIH AIDS FUNDING

Question. Would you please submit for the record, what each individual institute's original request for AIDS funding was for FY 1989.

Answer. The table below displays the amounts requested of the NIH by the Institutes during the 1989 preliminary budget.

| | |
|---|---|
| NCI | $129,952 |
| NHLBI | 42,852 |
| NIDR | 9,135 |
| NIDDK | 12,050 |
| NINCDS | 14,115 |
| NIAID | 394,945 |
| NIGMS | 43,000 |
| NICHD | 20,310 |
| NEI | 4,709 |
| NIEHS | 4,158 |
| NIA | 452 |
| DRR | 34,236 |
| NCNR | 707 |
| FIC | 2,000 |
| OD | 15,000 |
| TOTAL | $727,621 |

Question. And would each of the Public Health Service agencies, here today, submit their original budget request for the record.

Answer. Below are the individual PHS agencies' AIDS requests to PHS.

| | |
|---|---|
| FDA | $40,420 |
| HRSA | 64,268 |
| CDC | 291,852 |
| NIH | 565,209 |
| ADAMHA | 192,917 |
| OASH | 45,979 |
| Total | $1,200,645 |

Question. According to the FY 1989 budget justification, the number of full-time equivalent staff positions for NIH AIDS related work will increase by 70 over 1988. How does the increase in 70 AIDS positions compare to the original number requested by all of the Institutes for FY 1989?

Answer. The total number of FTE requested of the NIH byu the Institutes in the FY 1989 AIDS budget request was 640. The level in the 1989 President's Budget is 580 for AIDS.

Question. Dr. Fauci, how many FTE positions did you request for NIAID when you submitted your original budget request to the NIH budget office?

Answer. The Institute requested 175 FTEs in the initial budget request submitted to NIH for FY 1989.

Question. How many will you receive under the Administration's request?

Answer. The Institute would receive 148 FTEs for AIDS activities in the President's budget.

Question. What impact will limiting the number of AIDS FTE positions have on the AIDS research conducted through NIAID?

Answer. Although the President's budget does not provide us with the number of FTEs we originally requested for the expanded AIDS research effort that is planned for FY 1989, we will make every effort to maximize the usage of the FTEs provided to maintain the integrity of the AIDS program.

Question. What impact does it have on the non-AIDS research conducted at NIAID?

Answer. Non-AIDS research will not be affected by the decreased AIDS FTE allocation since the Institute is not redirecting any additional funding or staff from other program areas to support AIDS efforts. However, the decrease of 9 non-AIDS FTEs will have a direct effect on non-AIDS research activities such as vaccines, STDs, immunology, etc.

Question. Dr. Fauci, I understand concerns have been raised by clinical scientists about whether there are sufficient funds allocated to meet the costs of running an AIDS Clinical Trial Group (ACTG). How much will be spent on the ACTG in FY 1988?

Answer. The estimate for the ACTG in the 1988 column of the 1989 President's budget is $67.2 million.

Question. How much are you requesting for FY 1989?

Answer. The estimate for the ACTGs in the 1989 President's budget is $78.4 million.

Question. Was that your original budget request?

Answer. In the FY 1989 preliminary budget, we requested $87 million for the ACTG.

Question. Have the ACTG costs proven to be higher than you initially anticipated? If so, why?

Answer. Even though the AIDS Clinical Trials Group of NIAID has been actively recruiting patients for only slightly more than one year, and information available on its cost is preliminary, it is quite clear that the observed cost per patient accrued is very high relative to other similar programs of the NIH and of industry. There are clearly many factors involved in this difference. The following are worth highlighting: 1) management of AIDS patients poses an extremely complicated medical problem in which intercurrent illnesses and other complications frequently arise--in this setting the separation of treatment research from routine medical care, always difficult, is even more problematic; 2) the medical/nursing research component is more intensive because of the complexity of the illness; 3) special support is required for unique psychosocial needs in these patient populations; 4) a high proportion of individuals do not have health insurance and do not qualify for government-sponsored programs; 5) in addition, fear over loss of insurability leads a significant number of patients to deny availability or otherwise block utilization of third party reimbursement even when it exists; 6) the intensity and expense of required ancillary and monitoring laboratory studies is greater than required in most clinical trial settings; 7) it appears that third party payers are much more rigorous in the exclusion of costs which, in other settings, might be regarded as routine medical care unrelated to research.

The seven factors cited above require a research support program that includes a variety of personnel and other health-related services generally not included in the design of a traditional clinical trial program. Therefore, the requested budget does not reflect the magnitude of the differential between other established clinical trial programs and the ACTG. Since patient accrual has only been active for approximately one year, we are just beginning to see the differences and have initiated a study to examine the actual resource requirements. This study will attempt to address the factors involved in the apparent high cost as rapidly as possible.

Finally, it must be pointed out that there is one additional major programmatic uncertainty that enters into the projection of cost, namely, the balance of Phase I versus Phase III studies conducted by the group. Phase I studies require fewer patients and the costs per patient are higher, whereas Phase III involves a significant increase in the number of patients studied. The balance between Phase I and Phase III must shift, at any given point, based on the results of preclinical drug development. It is obviously impossible to predict where the future will take us in this rapidly moving area, especially when the future under consideration is one year or more away.

Question. How much more money would you need if you were to expand these units to provide for broader geographic availability?

Answer. Although there have been two rounds of competitive solicitation for selection of sites to participate in the AIDS Clinical Trials Group, there remains a need to make units available in such a manner that there is good geographic distribution across the United States. Geographic distribution of units is important for several reasons; a particularly important one is the desire to extend access to trials into satellite, community-based sites that are linked with more traditional units for purposes of quality control and data management. An example of this is the partnership currently existing with the Hemophilia Treatment Centers participating with AIDS Clinical Trial Units (ACTUs) in the conduct of protocol 036, the study of AZT in asymptomatic hemophilic subjects.

The NIAID is very interested in establishing ACTUs in major cities with significant infected populations and where there is no available unit at this time (e.g., Houston and Dallas, TX; Denver, CO; Atlanta, GA; and several other mid-Western cities). The current annual cost of an individual Unit in a major epicenter of the disease ranges from approximately $1.5 to $2.8 million.

## PRESIDENT'S COMMISSION RECOMMENDATIONS

Question. Dr. Windom, as you know, this past February the Presidential Commission on the Human Immunodeficiency Virus epidemic issued an interim report which included numerous recommendations for an integrated national strategy to deal with the AIDS epidemic. The interim report focused on three areas: new drug development; health care; and IV drug abuse treatment and prevention. I would like to ask you about a few of the Commission's recommendations.

The Commission has recommended the establishment of a "treatment on demand" system for IV drug abusers. The Commission estimates that such a system would cost $1.5 billion a year.

How much is the Federal government currently spending on IV drug treatment and what are the Department's plans for responding to the Commission's recommendation?

Answer. We do not have reliable information on total expenditures on drug treatment for the entire federal government. Since the adoption of the block grant mechanisms in FY 1982, we have had no reliable way of collecting information on the sources of funding for treatment. Furthermore, many of the sources of funding for treatment provided by the federal government do not require that a specific amount be spent on drug treatment. A fortiori, it is even more difficult to estimate the total cost to the federal government for IV drug treatment. Preliminary estimates would indicate that ADAMHA, IHS, DOD, and VA are planning to spend $367 million in FY 1988 and $425 million in FY 1989 for drug abuse treatment.

We have not yet had time to fully review the recommendations of the interim report of the President's Commission on AIDS as they pertain to a "treatment and demand" system for IV drug abusers.

Our understanding is that about $1.5 billion would be directly targeted toward drug abuse treatment--about half of that from federal and half from State and local support.

The thrust, although certainly not the magnitude, of the recommendations is consistent with the current Department directions--including our recommendation in the FY 1989 budget for a new $40 million grants program for IV drug abuse. Overall, ADAMHA is requesting $595.8 million in FY 1989 for drug abuse programs including treatment, research, prevention, and demonstrations, an increase of $73.1 million (+14%) over FY 1988.

FAMILY PLANNING REGULATIONS

Question. Dr. Windom, as you know I have been very concerned about family planning regulations that were issued by the Administration this past year. While the courts are considering these regulations, does the Department have any other plans to change the family planning program either through legislative proposals or administrative regulations?

Answer. The Department will soon send proposed legislation to Congress which would change the categorical family planning program to a State Administered Grant Program. The Administration's FY 1989 Budget Request reflects this proposal. There are currently no other legislative proposals or administrative regulation changes being planned.

TRAINING

Question. The FY 1989 budget justification calls for expanding the AIDS research training program to $5,738,000 which will support approximately 269 full-time training positions. How much of an increase is the FY 1989 budget over FY 1988?

Answer. The FY 1989 budget for research training programs associated with AIDS research of $5,738,000 and 269 trainees is an increase of $3,175,000 and 139 trainees over the FY 1988 estimate of 120 trainees and $2,563,000.

Question. Is additional money enough to attract both the young and the more senior scientists into AIDS research? Are there other disincentives to participating in AIDS research?

Answer. While additional funds for expanding AIDS research are critical for attracting both junior and senior scientists into AIDS research, there are other important factors that must be addressed. These factors include:

- o The commitment of a stable base of AIDS research support from the NIH through the research grant mechanism, so that young investigators at the point of making a career commitment perceive a path for career advancement and career stability in AIDS research.

- o For both junior and senior scientists, laboratory space for AIDS research is all too frequently not available at major research institutions since all in the medical research community agree that AIDS research initiatives should not be done at the expense of curtailing other research areas. Also, for those investigators willing to work with live AIDS virus, there are not enough available funds to build or renovate the required specialized highly protective facilities.

- A third major factor important in attracting both senior and junior investigators is the creation of Centers for AIDS Research. These centers would attract investigators from the multiple, diverse disciplines required to attack this disease. In FY 1988 the NIAID established a Centers for AIDS Research program. There has been tremendous enthusiasm expressed for this program by the research community, since it will accelerate the pace of AIDS research by allowing the synergistic efforts of multidisciplinary approaches.

- Another important resource limitation restricting the attraction of scientists into AIDS research is the availability of adequate numbers of animals for research. Much of AIDS research involves studies of the pathogenesis of the virus in animal models, and the testing of new drugs and vaccines in these models. The supply of such animals is severely limited. Consequently, an expansion of this resource will attract additional investigators in critical fields. This requires not only the animals themselves but additional facilities to house and breed them and to provide required veterinary care.

- Recruitment and retention of laboratory workers is emerging as a major problem for some laboratories working with the live virus. It is more costly to study a virus such as HIV, not only because of the additional protective facilities required, but also for the added training in protective measures necessary for workers in these laboratories.

- For clinical research it is forecasted that there will not be adequate numbers of health care providers to accomplish either research protocols or patient care as the epidemic grows in certain cities.

Question. What recommendations do you have for overcoming these problems?

Answer. It is recommended that the factors just cited be given careful consideration in developing an overall plan to attract and retain scientists in AIDS research.

Question. What efforts, if any, have been made, either at the CDC or through HRSA, to educate emergency workers (firemen, paramedics, etc.) about AIDS and the risk associated with the transmission of the AIDS virus?

Answer. The CDC has been designated as the Agency responsible for this training. HRSA did, however, include representatives of "first responders" (e.g. firemen, paramedics, etc.) in their multidisciplinary curriculum conference on (AIDS/HIV) infection for ETC held in the fall, 1987.

Question. Dr. Fauci, as you know, one of the recommendations that came out of the Institute of Medicine Conference on AIDS Drug Development was for the NIH to enhance its communication with the scientific community about ongoing research and new developments. I understand that the FY 1989 budget justification calls for creating a unit for scientific communication within the AIDS program. How will this unit be structured?

Answer. The Institute proposes in FY 1989 to create a unit in the AIDS Program comprised of a senior scientist writer and a support staff person to identify, obtain materials, and classify important ongoing resources and significant recent research findings in AIDS supported by the NIAID or by other sources. This unit will then coordinate with the NIAID Office of Communications in developing and implementing rapid research information dissemination to appropriate scientific community audiences. In addition, this unit will provide the Office of Communications with the expertise necessary in the development and editing of scientific information bulletins.

Question. Do you believe this will provide the link that will be needed to connect the NIH to the academic and private industry scientists?

Answer. This unit is seen as being only one link, although an important one, to connect the NIH to the academic and private industry scientists. Other important linkages to these scientific communities are the National Library of Medicine, the NIAID National Drug Discovery Groups (a consortium of academia, private industry, and government scientists), and publication in scientific journals by NIAID-supported investigators.

## AIDS - MINORITIES

Question. Dr. Windom, given the disproportionate number of persons with AIDS who are Black and Hispanic, would you agree that we should be increasing our efforts to provide AIDS education and prevention programs and services to the Black and Hispanic communities?

Answer. Information and education programs directly for minorities increase from about $7.5 million in FY 1987 to $29.7 million in FY 1988 and $36.2 million in FY 1989. In addition to programs aimed directly at minorities, PHS supports specific information and education programs aimed at the general public and at high risk populations. These programs increase from $152.3 million in FY 1987 to $333.7 million in FY 1988 and $447.0 million in FY 1989. See table on following page.

## PUBLIC HEALTH SERVICE

## AIDS-Information and Education
## Programs Indirectly Benefitting Minorities

| | 1987 | 1988 | 1989 | Estimated % of Funds Benefit. Minor |
|---|---|---|---|---|
| CDC | | | | |
| Expand National Public Information Campaign including design and develop special programs for minorities............. | $13,692 | $7,831 | $10,140 | 20% |
| Every Household Mailer..... | --- | 15,000 | --- | |
| Assistance to States and Communities for conducting local public information efforts................... | --- | 7,500 | 15,000 | >20% |
| Counselling and Testing.... | 26,039 | 72,165 | 102,376 | 40% |
| Health Education/Risk Reduction State Prevention projects........ | 21,454 | 21,197 | 28,492 | 30% |
| School Health Activities... | 11,076 | 29,916 | 36,450 | 20% |
| ADAMHA | | | | |
| NIDA - Information and Education aimed at high risk and infected 1/ ...... | 16,996 | 55,685 | 59,048 | 63% |
| NIDA - IV Drug Abuser Treatment and Demo. Activities 1/ ............ | --- | --- | 40,000 | 63% |
| NIMH - Publications........ | 139 | 837 | 1,560 | 15% |
| NIMH - Hlth. Care Workers.. | 1,981 | 4,180 | 5,372 | 10% |
| Total, Information and Education............... | $91,377 | $214,311 | $298,438 | |

1/ It is estimated that 63 percent of the IV drug abusers are minorities.

Question. Dr. Mason, how much are we spending in 1988 on specific AIDS activities for Black and Hispanic communities? How much are you requesting in 1989?

Answer. See table on previous page.

## OFFICE OF MINORITY HEALTH

Question. Dr. Windom, why have you essentially frozen the AIDS funding for the Office of Minority Health at $1.5 million?

Answer. The PHS agencies have a combined AIDS budget which contains a significant amount of funding for AIDS activities specifically targeted toward the minority population. The Office of Minority Health (OMH), through its participation on the PHS Executive Task Force on AIDS, can and does influence the way PHS agencies spend their appropriated AIDS dollars. The $1.5 million appropriated by the Congress for the OMH does not represent the only funding within PHS that addresses minority health issues. Therefore, we feel that the $1.5 million allows the OMH to initiate new activities that are not duplicative of other PHS activities that will have a positive impact on the minority population.

## DENTISTS

Question. This question is actually directed to Dr. Fauci, Dr. Mason and Dr. Sundwall.

What are your individual agencies doing to educate and train dentists about AIDS and AIDS infection control methods?

Answer. HRSA has initiated a number of activities to educate and train dentists about AIDS. These activities include:

- convening a dental workshop at which highly respected dental educators and practitioners were brought together to discuss and develop a report on the AIDS-related dental education needs (October 1987);

- convening a "Multidisciplinary Curriculum Development Conference on HIV Infection" at which the dental workshop report, as well as the reports from other medical professions workshops, formed the basis for discussions on curriculum development (November 1987);

- provision by AIDS regional Education and Training Centers (ETCs), funded by HRSA, which provide AIDS education and training to primary care health care providers. Dentists are included specifically as a target audience for these centers. Programs directed at dental providers have been conducted by the University of California at Davis Center and by the New York University Center; and

- provision of coordinated funding support, through an intra-agency agreement between the HRSA and the CDC, for the development of dental AIDS education curricula guidance by the American Association of Dental Schools.

Question. Are you concerned about the availability of dental services for those who are HIV positive or have AIDS?

Answer. The HRSA has substantial concern about the availability of dental services to this population. The dental health care worker (DHCW) provides important diagnosis, treatment and referral services to the HIV infected person. Initial signs of HIV infection, such as unexplained oral candidiasis and oral hairy leukoplakia, may be detected by the DHCW, leading to early referral and diagnosis. To date, more than 35 oral lesions have been identified as associated with HIV infection. Such lesions are reported to occur in up to 51 percent of patients with AIDS. Oral Kaposi's sarcoma is considered virtually to be pathognomonic of AIDS in males aged 25-44 years. HIV infected individuals will seek treatment for these and other "commonplace" oral conditions not necessarily related to HIV infection. The DHCW will be expected to provide relief from pain and discomfort and to palliate or eliminate oral disfunction, with the goal of improving the quality of life of HIV infected individuals.

Currently, in California, for example, it is estimated that every dental office sees at least two HIV infected persons each month, with that number increasing steadily. For those seeking care, DHCWs must be cognizant -- in addition to their role in direct service delivery -- of their responsibilities in the prevention of HIV transmission and in the coordination of health care with other providers. Access to oral health services of HIV infected persons, however, may be limited as a result of financial barriers and because of reluctance on the part of DHCWs to serve HIV infected persons. Although the stated goal of national DHCW organizations is to assure access to oral health care through full participation of private sector DHCWs, a few dental facilities operated by local community organizations and public agencies and by training institutions have been developed in an effort to address the HIV infected persons' unmet demand for dental care.

Question. What recommendations do you have for insuring that these services are provided?

Answer. There are a number of things we are doing or could do:

1. Continue to utilize the Service Demonstration Grant program to assure the development of various models for providing adequate, coordinated oral health services to people infected with HIV. Currently five projects have a dental component.

2. Continue to utilize programs such as the National Health Service Corps and the Community and Migrant

Health Programs to expand oral health care to populations which currently have inadequate dental health personnel or services and which have high prevalence of HIV infection.

3. Develop a strategy (utilizing national DHCW professional organizations and training institutions) to encourage the DHCW in the private sector to participate in the delivery of oral health services to HIV infected persons.

4. Incorporate oral health services into the HIV research agenda. The research agenda should assess the extent of oral health needs; the costs associated with the provision of adequate, accessible oral health services, and the impact of such services on health outcomes and the quality of life of the HIV infected person.

5. Encourage programs providing health services to HIV infected individuals to integrate DHCWs as active participants in the delivery of coordinated, case-managed care and in the provision of counseling and other services related to containing the spread of the infection.

## CLINICAL TRIALS

Question. Dr. Fauci, how many drugs are currently being tested in clinical trials? What drugs are being tested?

Answer. Currently there are 17 drugs in clinical trials and 16 drugs in the protocol development phase. The drugs that are being tested in clinical trials and those that are in the development process are listed below:

A. Drugs Being Tested in Clinical Trials

Acyclovir
Aerosolized Pentamidine
AL 721
Alpha Interferon
AZT
AZT plus combination chemotherapy
DHPG (Ganciclovir)
Dideoxycytidine (ddC)
Doxorubicin
Fluconazole
Foscarnet
Gamma Interferon and Tumor Necrosis Factor
IL-2 (Interleukin 2)
Intravenous Immune Globulin (IVIG)
Probenecid and quinine in combination with AZT
Trimethoprim/Sulfamethoxazole
Trimetrexate

B. Drugs in Development Process

Ampligen
AS101
Beta Interferon
Clindamycin + Primaquine
Dapsone
Dextran Sulfate
ddA (Dideoxyadenosine)
ddI (Dideoxyinosine)
Eflornithine (DFMO)
Erythropoietin
GM-CSF (Granulocyte-macrophage colony stimulating factor)
Isoprinosine
LAK Cells
Pyrimethamine-Sulfadoxine
Ribavirin
Soluble T4

Question. How many clinical trials are currently ongoing?

Answer. There are 24 active protocols in the clinical trial program.

Question. Do any of the trials include women?

Answer. All of our trials are open to women; and as of April 18, 1988, there were 161 women in various studies we are conducting. It is a very clear working policy of the Institute that a person's sex, in and of itself, has no bearing on eligibility for participation in a clinical trial. We believe that this represents a good example for other sponsors of clinical trials around the country. At the present time, 5 percent of the patients enrolled in NIAID-supported clinical trials are female. Nationally, 8 percent of AIDS cases reported to the CDC have occurred in females. To interpret these figures properly, it is important to note that approximately one-half of AIDS cases in females are related to intravenous drug abuse. Active intravenous drug addiction represents a serious concomitant medical disease that may affect the tolerance and response to research drugs. The reasons for exclusion of female IV drug users to date are twofold: first, as a population their reliability in compliance with a research protocol regimen may be low, and they are often lost to follow-up or drop-out; secondly, active intravenous drug users are extremely likely to develop serious medical problems unrelated to the research treatment. We emphasize that these methodologic considerations apply only to active intravenous drug users, but understanding them is crucial to a proper interpretation of the very small disproportion between representation of women in NIAID clinical trials and the fraction of AIDS cases that occur in women. We continue to examine this situation further, are encouraging investigators to include an appropriate proportion of females, and are exploring innovative approaches to increase the number of women in clinical trials.

Question. Will the trials include women in 1989?

Answer. Yes, the trials will include women. However, all of our trials using experimental drugs require that women of child bearing age practice adequate birth control.

Question. Do any of the trials include IV drug users? Children?

Answer. As of April 18, 1988, there were 364 patients who were previously using IV drugs and 12 who are currently using IV drugs. In trials sponsored by NIAID and NICHD there are 130 pediatric patients enrolled.

Some studies are specifically being conducted in pediatric populations. In fact, a Phase I trial of AZT in children has recently been completed. The results of this study are encouraging enough to justify the initiation of a larger study of AZT in very sick children in which the efficacy of the drug will be compared to an historical control group of untreated children. This analysis will be much more difficult than in a placebo-controlled study, but it is hoped that the existing control data (which has been examined) will be adequate. In addition, additional pharmacokinetic studies in neonates must be done; and placebo-controlled studies in children with less severe infection are also planned.

The pediatric trials are limited to children, with specific limits on age. Safety concerns dictate that older children be studied first, lowering the minimum age requirement as appropriate, until newborns can also be treated.

The NIAID currently supports pediatric studies at a limited number of the AIDS Clinical Trial Units. In addition, we have developed a Request for Applications for expansion of the Pediatric AIDS Clinical Trials Group, and have received 27 applications from institutions that want to join the Pediatric AIDS Clinical Trials Group; these applications will be reviewed in June 1988.

Question. What is the NIAID doing to recruit women, IV drug users and children into its clinical trials?

Answer. The NIAID is currently meeting with representatives of women and minority groups to develop plans to recruit women, minorities, and IV drug users into clinical trials. A formal plan and agenda for recruiting women, minorities, and drug users into clinical trials will be developed in the near future. This plan will include consideration of such factors as: requirements for geographic location of clinical trial sites accessible to minority groups; development of training manuals and training for clinical trials personnel on outreach, and special services requirements for women, minority groups, and IV drug users; and, costs of expanding clinical trials to meet the special needs of women, minority groups, and IV drug users.

The Institute is also working with the National Institute on Drug Abuse (NIDA), ADAMHA, regarding defining issues and developing plans for recruiting IV drug users into its clinical trials. On May 17, 1988, NIDA will be presenting a formal seminar to the NIAID on this issue. An action plan will be developed regarding recruitment of IV drug users into clinical trials. The NIAID will also solicit the input and expertise of state and local drug abuse administrators and drug abuse treatment representatives from state/localities that have NIAID-supported clinical trials. The NIAID plan on recruitment of IV drug users into clinical trials will include such factors as identification of IV drug users with HIV/AIDS and special outreach mechanism to IV drug users, drug treatment programs, and health clinics to recruit IV drug users into clinical trials. Consideration of special services required to recruit IV drug users and to maintain their participation in clinical trials, supporting cooperative relationships between clinical trials sites and local community agencies/programs that serve IV drug users, and costs associated with including IV drug users in clinical trials will also be explored and defined.

In addition, the NIAID issued a Request for Applications specifically directed toward pediatric AIDS clinical trials to conduct therapeutic studies in younger populations infected by HIV. Twenty-seven applications were received, and they will be reviewed in June.

Question. The President's AIDS Commission has recommended that the NIAID staff for clinical trials should be increased from 47 to 120. How many FTEs are requested in the President's budget for NIAID clinical trials for FY 1989?

Answer. Increased FTEs for AIDS clinical trials were not specifically identified in the President's budget. The budget reflects a total of 148 FTEs for all AIDS activities.

## CO-FACTORS AND AIDS

Question. Dr. Fauci, I understand there is a great deal of interest in determining how certain co-factors may affect the transmission of the AIDS virus or the progression of the disease?

Answer. The concept of co-factors in the transmission of HIV infection stems from epidemiologic studies which have shown an association between several sexually transmitted diseases and HIV infection in this country and in Africa. A particular association of genital ulcer disease with HIV infection in Africa has led to the development of the theory that damage to genital skin and mucous membranes may facilitate transmission of the virus.

The difference in the epidemiology of HIV infection and disease progression in Africa as compared with Europe and North America has led to formulation of questions concerning what the effect of the multitude of endemic diseases is on the progression of HIV disease in individuals who are infected.

Question. What do we know about co-factors and what kind of research is the NIH conducting related to co-factors and AIDS?

Answer. In vitro studies have helped to answer questions relating to the possible effect of co-factors on the progression of the disease. In vitro experiments have shown enhanced expression of the HIV virus in T cells after being infected with DNA viruses or activated with mitogens. In the Multicenter AIDS Cohort Study (MACS), cytomegalovirus antibody titers were found to be strong predictors of the development of frank AIDS in HIV infected individuals, and consequently, a possible co-factor.

Several studies are currently being designed to study the effect of multiple infections and co-factors on the transmission and progression of HIV disease in both Africa and Latin America. The effect of possible co-factors will also be studied in several cohort studies of homosexual, heterosexual, and perinatal transmission supported by NIAID.

## PHASE III CLINICAL TRIALS

Question. On page 120 of the FY 1989 budget justification a new program is proposed to establish a group to perform Phase III clinical trials. Do you expect that an AIDS vaccine could be in a Phase III trial during FY 1989?

Answer. It is uncertain at this time whether the two vaccine candidates currently undergoing or about to undergo Phase I testing will, in fact, proceed into Phase III or whether there will be other vaccine candidates (now in the development stage) appropriate for clinical evaluation.

Question. How much money will be spent on this group and what will this group be doing?

Answer: For a number of years the NIAID has supported at least 6 vaccine evaluation units (VEU), which serve as an important component in the vaccine development process. The VEU are groups of investigators who specialize in evaluating vaccines in the earliest stages of development by conducting Phase I and II trials to determine antigenicity and general safety. When preclinical testing in the laboratory has shown good results, a candidate vaccine is provided to one or more of the VEU to undergo this early testing in humans. Through these first clinical studies, problems can be detected; and the information is then used to redesign the vaccine, if necessary. Some of the existing units focus on adult immunization and have been testing, for example, influenza and hepatitis vaccines; others focus on pediatric studies such as testing attenuated vaccines for respiratory syncytial virus and rotavirus. Still another group has the capacity to conduct volunteer challenge studies in which a volunteer is immunized and then challenged with the infectious organism, e.g., cholera, rotavirus, and malaria. To date these Units have not been set up to conduct Phase III studies that involve large numbers of subjects.

The plan is to expand this effort by establishing about 4 additional units that will focus on clinical evaluation of AIDS vaccines and provide the base for conducting Phase III trials at some point in the future. The FY 1989 President's budget reflects about $10,550,000 for these additional units.

### HIV PREVALENCE STUDY

Question. On page 143 of the FY 1989 budget justification, the Department states that the NIAID plans an "initiative to determine the prevalence of HIV in the U.S. population." Are you coordinating this initiative with the CDC family of surveys?

Answer. The feasibility of measuring the course of the HIV epidemic by determining the seroprevalence of HIV antibody in women of childbearing age has recently been demonstrated in a pilot study in Massachusetts. It should be noted that this methodology is quite attractive in that it utilizes blood samples that are already being collected on infants born in the United States to test for other metabolic and infectious diseases of newborns (such as phenylketonuria, congenital hypothyroidism, and congenital toxoplasmosis). Because of the nature of the HIV antibody (which is known to cross the placenta from mother to infant), the antibody status of the infant directly reflects the antibody status of the mother. Changes in the prevalence of infection in women of childbearing age could therefore be followed over time, and provide a practical means of tracking the epidemic in the general population. Current plans to expand this program to other states are underway.

Question. Is the NIAID initiative any different from the studies currently ongoing at the CDC?

Answer. NIAID is coordinating this effort with both the National Institute of Child Health and Human Development (NICHD) and the Centers for Disease Control (CDC); all three are jointly sponsoring the national study.

### REPOSITORIES

Question. On page 144 of the budget justification, there is a description of the development of a repository for research materials funded in the NIAID.

On page 157 of the budget justification, there is a description of efforts in the Office of AIDS Research.to acquire purified HIV protein.

How do these two programs differ and how much money will be spend on each in FY 1989?

Answer. The program within the Office of the Director to develop targeted antiviral agents for the treatment of AIDS depends on the acquisition of purified HIV protein. Out of a requested FY 89 budget of $9.1 million, $1.1 million would #e required to purchase such proteins when they become available.

These proteins would not be placed in a repository but would be procured as reagents for immediate use in participating NIH intramural laboratories.

In contrast, the NIAID repository for research materials is intended to be a national resource for AIDS researchers (including NIH intramural scientists) who need reagents or other materials to accomplish their work. However, it is not expected that this repository will include purified HIV proteins in sufficiently large quantities for the structural studies required in the NIH intramural targeted antiviral program. The program budget for the repository for FY 1989 is $2.2 million.

## VACCINE TRIALS

Question. How many people are participating in each Phase I trial of an AIDS vaccine.

Answer. At the NIH Clinical Center, the Phase I trial of a subunit recombinant protein (gp 160) will accrue a total of 81 persons to evaluate safety and immunogenicity. In the Phase I trial of the same product currently under investigation at the NIAID Vaccine Evaluation Units, 72 persons will be entered into the trial.

Question. What is the minimum number of people needed in a Phase I trial to obtain the information you need?

Answer. The number of persons necessary for evaluation of a vaccine in Phase I is based on the endpoints being examined in the trial. For AIDS vaccines, safety and immunogenicity of the product will be determined in Phase I. The NIAID is currently sponsoring two Phase I studies of human immunodeficiency virus gp 160 in different population groups in order to ascertain the answers to these safety and immunogenicity issues. In general, safety can be ascertained with as few as 10-20 persons, however, immunogenicity questions require that the number of persons be expanded. This is particularly true for the AIDS vaccine trials, where a more comprehensive analysis of immunologic parameters will be done than for any previous study. In the Phase I trial being carried out at the Vaccine Evaluation Units, there are 4 groups of 18 volunteers who will receive either a placebo, a hepatitis B vaccine as a comparative vaccine control group, gp 160 at a low dose, or gp 160 at a higher dose. The necessity for 72 persons in this trial is based on the minimum number of persons required to compare immunologic and hematologic parameters that are vaccine induced to controls.

## MULTICENTER AIDS COHORT STUDY

Question. Dr. Fauci, would you describe what is being done in the multicenter AIDS cohort study, often referred to as the MACS study?

Answer. Researchers involved in the Multicenter AIDS Cohort Study (MACS), a longitudinal study of a cohort of approximately 5000 homosexual/bisexual men initiated in 1984, are currently conducting biannual assessment of behavioral, clinical and laboratory parameters of HIV infection and disease progression.

The large sample size of this epidemiologic study has provided public health information of critical importance. Risk factors for HIV infection have been clearly established. Several important conclusions have already been reached from the study, including the identification of behavioral risk factors for transmission of the virus, and laboratory and clinical markers that can predict the development of AIDS among HIV sero-positive individuals.

Currently, investigations are focusing on the determinants of clinical outcomes (e.g., variations in the virus, the effects of co-factors, and ethnic factors), and the severity and spectrum of disease expression (e.g., neurologic sequelae). The MACS also affords the opportunity to investigate, in depth, the immunopathogenesis of the virus in a large, well defined cohort of patients. This has and will continue to provide critical baseline data for stratifying patients in our vaccine and clinical trials. The availability of catalogued banked sera on this large cohort, which is associated with a large data base, is and will continue to provide a valuable source for studies of many problems associated with AIDS transmission and pathogenesis. One application that is currently being pursued is the investigation of improved diagnostic techniques that will enable earlier diagnosis of infection. This has obvious implications for our national blood supply.

Finally, this study is providing sound epidemiologic data that is imperative for predicting public health needs with clear implications for our national health policy.

Question. How much will be spent on the MACS study in 1988?

Answer. In FY 1988, it is estimated that we will obligate about $10 million on the MACS.

Question. How much has been requested for FY 1989?

Answer. Approximately $11 million was requested for the MACS in the FY 1989 President's budget.

Question. Is the information gathered from this study available to all the public health agencies?

Answer. Through representation of NIAID program staff on the various AIDS task forces of the Public Health Service (e.g., Epidemiology Task Force chaired by Dr. Curran of CDC), up-to-date information from the MACS is presented and discussed on a routine basis. The timely dissemination of research findings from the MACS has provided important information for policy and planning (e.g., MACS data from neuro-psychiatric studies was made available to Dr. Fischinger of the PHS). In addition, the NIAID maintains a current bibliography of abstracts and publications from the MACS and responds to requests for this information.

Question. If so, should other agencies be conducting studies to determine the natural history of AIDS?

Answer. The MACS will continue to provide invaluable data on the natural history of HIV infection in a large cohort of homosexual/bisexual men. Clearly, it is imperative that we conduct similar natural history studies in other populations at risk of HIV infection, e.g., IV drug abusers, heterosexuals, infants of HIV-infected mothers. Such studies are planned, or underway, within the various Institutes of the National Institutes of Health. Other agencies of the PHS (e.g., CDC's Hepatitis B cohort and NIDA's IVDA cohorts) have established cohort studies that will also continue to provide invaluable data.

## HETEROSEXUAL STUDIES

Question. What kind of studies is the NIAID planning to conduct to acquire information about the rate and risk of heterosexual transmission?

Answer. To date, most heterosexual transmission in the United States has occurred among sexual partners of intravenous drug abusers. Fewer numbers of cases have occurred among sexual partners of recipients of contaminated blood products and female sexual partners of bisexual males. Whether there is any significant amount of heterosexual transmission occurring outside of these groups is unclear at this time; however, the experience in Africa and Haiti certainly speaks to the potential for heterosexual transmission in the general population.

Therefore, it is very important to thoroughly understand all aspects of heterosexual transmission of HIV, both in developing countries and in the United States. Accordingly, NIAID recently initiated several programs that will specifically study heterosexual transmission. The first of these initiatives led to the awarding of grants to 5 research institutions in 5 cities in the United States in 1987 (New York, Los Angeles, Miami, Providence, and San Francisco) to study the basic epidemiology of HIV infection among heterosexuals. These grantees will study several thousand individuals who may be at risk of acquiring heterosexually transmitted HIV infections (partners of IV drug users and bisexual males, prostitutes, clients of sexually transmitted disease clinics, etc.). Particular emphasis will be placed on discerning risk factors for transmission of HIV.

Within the next several months, NIAID will also award contracts to two additional institutions to establish a large study cohort of heterosexual men and women at risk of HIV infection. It is hoped that the large numbers of subjects enrolled in this multicenter study will allow researchers to discover risk factors that facilitate transmission and other factors that might protect against transmission (such as use of barrier contraceptives). This large contract study will also examine in detail the natural history of HIV infection in heterosexual populations.

Two additional studies will indirectly provide information on heterosexual transmission in the United States. The NIAID is collaborating with the NICHD and the CDC to develop a national project to look at the prevalence of infection in mothers by using blood specimens obtained from newborn infants in a completely anonymous fashion. If a newborn tests positive for the AIDS antibody, it means that the mother is infected. Data generated from this national study may be extrapolated to an understanding of the extent of infection in all women of childbearing age. This is an important group because these women for the most part become infected through either heterosexual contact or intravenous drug use. Within the next several months, NIAID is also planning to award 3 contracts to research institutions in the United States to specifically study risk factors for perinatal transmission and natural history of HIV infection in children born to HIV positive women. This multicenter study of more than a 1,000 women and children will also examine possible risk factors for transmission in the mothers, thus providing additional information on heterosexual transmission.

In order to better understand heterosexual transmission in developing countries, in July 1988 NIAID expects to award grants to five U.S. research institutions to engage in collaborative research with overseas counterpart institutions in Africa and Latin America. This new initiative has been named the International Collaboration in AIDS Research (ICAR) program. Four of the five centers have specifically targeted heterosexual transmission as an area of study. It is hoped that a better understanding of mechanisms of heterosexual transmission in areas where heterosexual transmission is a major problem will allow better understanding of the potential for heterosexual transmission in developed countries such as the United States and in Europe.

Question. Dr. Mason, is the CDC planning any such studies?

Answer. CDC has ongoing studies on heterosexual transmission of HIV from infected hemophilia patients and IV drug abusers to their sex partners. In addition, CDC has awarded cooperative agreement funds in FY 1988 to blood banks to expand studies of transmission between infected transfusion recipients and their partners. Additional funds for heterosexual transmission studies will be announced in an RFA to be published this spring.

## ADOLESCENT FAMILY LIFE

Question. Dr. Windom, just last month an article in the New York Times reported that a Pregnancy Distress Center in Columbus, Ohio, receiving $119,000 from the Adolescent and Family Life Program, was urging young women to "open your heart to God" and to visit a local church for further counseling. The Center also distributed a variety of religious oriented pamphlets.

As you know, the Supreme Court is currently considering the constitutionality of the Adolescent Family Life Act and the Senate Labor and Human Resources Committee will soon be considering new reauthorization proposals.

My question to you, Dr. Windom, is why has the Administration requested the same level of funding for the program in 1989 as in 1988 when last year the Department's budget documents stated: Funds requested in FY 1988 are requested with the aim of phasing out the program by FY 1990.

If you were planning to phase the funding out why aren't you proposing a cut below 1988?

For all the other programs proposed to be phased out, cuts were imposed. For example: Protection and Advocacy for the Mentally Ill and the Community Services Block Grant Program.

Answer. First, I would like to clear up the apparent misunderstanding about the Adolescent Family Life (AFL) grant to the Pregnancy Distress Center of Columbus, Ohio, since the New York Times story contained some misleading information. The AFL grant to the Pregnancy Distress Center exclusively supports educational services for nonpregnant teens only. These services are delivered by local schools and community organizations. There are no grant funds provided to support services to pregnant teens. Therefore, although the Pregnancy Distress Center may provide religiously oriented counseling or materials to pregnant teens with their own private funds, none of these activities are part of, nor have they been supported by, the AFL project.

The Department is not planning to phaseout the Adolescent Family Life program at this time. Last year's proposal for phaseout was reversed for several reasons. First, the President's Task Force on Adoption strongly supported continuation of the program because of its focus on adoption as a positive alternative to early parenting. The AFL program is the only Federal program focused exclusively on the problem of teenage pregnancy. Also, it became apparent that there have been very positive responses to what the program is accomplishing, for example, several States have developed and funded their own teen pregnancy programs based on new approaches developed by AFL funded projects.

The requested funding level for FY 1989 will permit continuation support for all grantees until the end of their project periods and will also fund 19 new demonstration and 6 new research awards.

## CENTERS FOR DISEASE CONTROL

### STATEMENT OF DR. JAMES O. MASON, DIRECTOR

ACCOMPANIED BY:
DR. WALTER R. DOWDLE, DEPUTY DIRECTOR
DR. ALAN R. HINMAN, DIRECTOR, CENTER FOR PREVENTION SERVICES

### INTRODUCTION OF ASSOCIATES

Senator CHILES. Dr. Mason, now, if I can switch over and get your oral statement, we will take your full statement and put it in. But from the Centers for Disease Control, Dr. Windom, we will excuse you now.

We know that in addition to the AIDS-related activity, the Centers for Disease Control is responsible for prevention, control, research, and training activities related to childhood immunization, sexually transmitted diseases, infectious diseases, chronic environmental disease, protection, occupational safety and health, and academic services.

In considering the 1989 budget request, the subcommittee is concerned about several issues. Among them is the impact of AIDS funding on the operation of the non-AIDS-related programs, and the explosive increases in sexually transmitted diseases, such as syphilis, and our efforts to stop these increases through the STD grant program.

We want to thank you for appearing before the subcommittee chaired by Senator Bumpers in March to discuss the impact of the vaccine excise tax on the childhood immunization program. And we have a few followup questions for you on that subject, if you will introduce your associates and proceed.

Dr. MASON. On my right is Dr. Walter Dowdle, who is the Deputy Director of CDC, and on my left is Dr. Alan Hinman, who is the Director of the Center for Prevention Services. We are delighted to be here to support the fiscal year 1989 budget request for CDC.

You have received our written testimony, and if that could be submitted for the record I will make a few observations.

First, I want to remind everyone that CDC is the Federal agency responsible for prevention and control of diseases, including AIDS, within the United States. So our focus is largely prevention and control.

You have already discussed the expenditures for health services. Treatment of disease, injury, disability in the United States amounts to over 10 percent of the gross national product. That is about $500 billion a year.

Our Nation, unfortunately, is not optimizing what can be done to prevent disease, injuries, disability, and premature death. Interventions exist which will decrease the need for treatment.

Opportunities to enhance the productivity of the Nation and to improve the quality of life are not being grasped. There are impressive cost benefits associated with these prevention interventions.

We have talked about immunizations to prevent infectious disease in children. This is just one example of what prevention can do to reduce health care costs, disability, and premature death.

There are many equally powerful interventions that can be applied toward the health of infants, children, and adults, which would give this Nation a highly favorable return on investment. For example, in selected cancers and other chronic diseases, injury prevention, and disability prevention.

We spent a lot of time on AIDS today. It is an important disease. But we have to keep reminding ourselves that there were unfinished health agendas before 1981, and those unfinished health agendas continue through today.

## PREPARED STATEMENT

And so I agree with your earlier statement that AIDS must not deter this Nation from its other health responsibilities, and achievable objectives. Thank you. We would be happy to answer any questions.

[The statement follows:]

# STATEMENT OF DR. JAMES O. MASON

Mr. Chairman and Members of the Committee: It is a pleasure to be here to support the Fiscal Year 1989 budget request for the Centers for Disease Control (CDC).

This Nation's public health system is built on a partnership of public and private health organizations, the former including local, State and federal government agencies or departments. This structure--characterized by interdependence and cooperation--has at its foundation individual physicians, local clinics and community hospitals. It is at the local level that illnesses are diagnosed and treated and notifiable illnesses of public health importance are reported for national surveillance purposes. Preventive services are most effectively delivered at the local level. In our country, this is the heart of public health action. CDC's programs assist local health officials to provide a wide range of essential prevention programs.

Through epidemiologic investigations, disease and risk factor surveillance, laboratory research, applied behavioral science, and capacity building at State and local levels, we provide national leadership in what has been called a "people-to-people" approach to public health.

The President's FY 1989 Budget requests $523,146,000 for prevention, control, research, and training activities of the Centers for Disease Control. This amount does not include the $400,719,000 proposed to be allocated to CDC for AIDS research and education which is included in the consolidated AIDS budget request of the Office of the Assistant Secretary for Health.

The CDC budget request provides a net increase of $6,671,000 for immunization grants which will allow us to provide the same number of vaccine doses as in 1987 and 1988. It includes $4,500,000 as a one-time expense, for the upgrade of the CDC mainframe computer system and $500,000 to fund the National Vaccine Program. It maintains funding for essential activities to control and prevent sexually transmitted diseases, infectious diseases, injuries, chronic and environmental diseases, and to support prevention research centers, occupational safety and health, and epidemic services. Consistent with the Bipartisan Budget Agreement, the President's FY 1989 Budget preserves essential public health programs.

The budget request does not include funds to increase the vaccine stockpile. It does include two-million dollars to fund the Prevention Centers during FY 1989 and 1990, after which time the Centers are expected to maintain their funding from other sources. The budget proposes a 3-year transition to industry and State funding for the National Institute for Occupational Safety and Health (NIOSH) Educational Resource Centers.

The following testimony includes highlights of CDC's recent accomplishments.

## IMPROVEMENT OF HEALTH FOR MINORITY AMERICANS

At a time when the health of most Americans is better than ever before, many minority citizens are suffering from disease, disability and premature death. The gap in health status is evident in the chronic diseases. Blacks over 45 are 50 percent more likely to die than whites before age 70. Almost 55 percent of the excess deaths result from four chronic diseases-- cardiovascular disease, cancer, diabetes and cirrhosis. AIDS attacks minority men and women and children in disproportionate numbers. Fifty-four percent of all AIDS cases under 13 years at the time of diagnosis are black, and 22 percent are Hispanic. This means that 76 percent of all children with AIDS are minorities. Among cases in women, 52 percent are in blacks, and 17 percent in Hispanic women. CDC is attacking these health problems on many fronts. We are recruiting an Assistant Director of CDC for Minority Health Programs to provide leadership in this area.

## CHRONIC DISEASE PREVENTION AND CONTROL

Last year I outlined CDC's integrated approach to preventing chronic diseases--the leading cause of death and long-term disability in our society. This year I will describe specific projects CDC is undertaking to prevent cardiovascular disease, cervical cancer, and smoking-related disease and similar conditions. Approximately 45 percent of all cardiovascular disease deaths, 28 percent of cancer deaths, and over 50 percent of the debilitating complications of diabetes could be prevented.

### Cervical Cancer

There are 6,800 women who die from invasive cervical cancer each year, almost 20 deaths per day. Recent Congressional interest has questioned the adequacy of Pap smears for cervical cancer detection. There is also limited access to screening and inadequate medical followup for many women, particularly the elderly and minorities.

With full access to screening, quality laboratory services, and with complete medical followup, NO women should die from this disease. The Center for Environmental Health and Injury Control (CEHIC) has established cervical cancer projects to demonstrate prevention techniques with three State health departments--Georgia, Illinois, and Kentucky. These projects will determine why diagnosis of cervical cancer is not made at an earlier stage when the disease can be most effectively treated.

### Smoking-Related Diseases

Smoking is the leading cause of preventable illness and death in the U.S. Results of the 1986 Adult Use of Tobacco Survey show that smoking among adults is the lowest ever recorded in the U.S.--26.5 percent. Though this is good news, cigarette smoking still causes an estimated 320,000 premature deaths per year. Helping addicted adults to quit smoking is much more difficult than encouraging teens not to take up the habit. To add to the impact of quality school health education, the Office on Smoking and Health, Center for

Health Promotion and Education, co-sponsored with 39 States a public service television announcement aimed at teens and distributed "Quit Smoking" posters for schools in 42 States.

## Diabetes

Diabetes, another chronic disease, causes an estimated 128,000 years of potential life lost from premature deaths before age 65 each year. Diabetes results in 25 million hospital days and approximately $8 billion in direct medical costs each year. In 1987, the National Diabetes Advisory Board recommended CDC as the lead Federal agency to translate the results of diabetes research into prevention-oriented patient care. The Center for Prevention Services is working with State health agencies to prevent major complications associated with diabetes. This program has resulted in third-party reimbursement for diabetes program activities in 19 State programs.

## Work-Related Diseases

Eight of the "Ten Leading Work-Related Diseases and Injuries" identified by the National Institute for Occupational Safety and Health (NIOSH) are chronic diseases. In the past, epidemiologic studies of workers have focused mainly on cancer and lung diseases. Renal disease has been diagnosed among workers heavily exposed to cadmium. Another NIOSH study of bridge and tunnel workers showed a significant excess of deaths from cardiovascular disease--the result of exposure to carbon monoxide. Results from these and similar studies lead to reductions in exposure of workers to hazardous substances in the workplace.

## INJURY PREVENTION

Injury is the leading cause of death for persons 1 to 44 years of age and the leading cause of disability in children and young adults. In addition to the human misery, injuries cost $75-100 billion each year. CEHIC conducts epidemiologic studies and surveillance activities related to non-occupational injury. For example, epidemiologic research regarding hazards of all-terrain vehicles led to a decision by the Consumer Product Safety Commission to stop the sale of three-wheel all-terrain vehicles.

CEHIC is developing recommendations that address ways in which communities can prevent an epidemic of suicides among young people. The rate of suicide among 15 to 24 year olds--over 5,000 deaths each year--increased nearly three-fold over the past three decades. Analysis of youth suicide clusters in two locations in Texas identified a number of common risk factors which are associated with youth suicide: frequent moves, exposure to traumatic deaths, family instability, and legal problems. These findings will add to the development and targeting of more effective programs to prevent teen suicides.

## NATIONAL CENTER FOR HEALTH STATISTICS JOINS CDC

In 1987, the National Center for Health Statistics (NCHS) was transferred from the Office of the Assistant Secretary for Health to CDC. With this addition we will be able to expand our capacity to monitor health trends and measure progress toward "National Health Objectives for the Year 2000." Data provided by NCHS serve as the basis for health research, health legislation, prevention and treatment, health planning, population projections, and health insurance planning. NCHS is preparing for the third National Health and Nutrition Examination Survey (NHANES III). A six-year study begins this fall.

This study is the cornerstone of the National Nutritional Monitoring System. Its data have been used in the past for many policy decisions in health and nutrition programs.

## AIDS--CONTROL AND PREVENTION OF HIV INFECTION

CDC has received reports through April 11, 1988, of 59,287 cases of AIDS and 33,060 deaths in the U.S. since 1981. Between one to one and one-half million Americans are estimated to be infected with Human Immunodeficiency Virus (HIV). CDC's comprehensive program to prevent the spread of HIV infection primarily includes:

- Surveillance
  - Tracking AIDS and HIV infection
- Epidemiology and Laboratory Studies
  - Investigating routes of virus transmission and outcome of infection
- Prevention
  - General Information and Education
  - Risk Reduction
  - Education of School and College Age Youth

CDC's AIDS budget for 1988 was $305 million, and the request for FY 1989 is $400 million. In 1987, 78 percent of CDC's AIDS funds went to support activities conducted by State and local health and education agencies, national organizations, and private businesses.

### Surveillance

AIDS surveillance systems allow the States and CDC to monitor disease trends, provide demographic data to target programs, and to evaluate prevention efforts. Highlights for FY 1987 include:

- Completed plans for the HIV seroprevalance program.
  - Pilot test for a National Household Seroprevalence Survey.
  - "Family of Surveys" including sentinel surveillance in 30 SMSA's (hospitals, sexually transmitted disease clinics, drug treatment clinics, family planning clinics, tuberculosis clinics, and women's health clinics) and special surveillance projects using data from such sources as the military, blood banks, Job Corps and colleges.
- Revised the clinical definition of AIDS.
  - Included a broader range of specific AIDS-indicative diseases.

  - Included presumptively diagnosed indicator diseases.
  - Eliminated exclusions due to other causes of immunodeficiency.
- Evaluated performance of HIV testing in U.S. laboratories.

## Epidemiology and Laboratory Studies

Epidemiologic and laboratory studies have demonstrated how HIV infection is and how it is not transmitted. Highlights for FY 1987 include:

- Funded 19 collaborative studies to increase scientific understanding of AIDS in various populations including:
  - Homosexual/bisexual men, prostitutes, IV drug abusers, and heterosexual partners.
  - Children/adolescents and family members.
  - Transfusion recipients and hemophilia patients.
  - Health-care workers.
- Multiple-center studies of household contacts of infected hemophilia patients.
- Application of the DNA amplification technique for more rapid detection of infection.
- Laboratory surveillance for new AIDS virus variants.
  - Established a system for HIV-2 detection which identified the first person in the U.S. to be infected.
  - Evaluating diagnostic tests for HIV-2.

## Risk Reduction

In 1987, CDC expanded assistance to States to support testing facilities as sources for counseling, testing, and partner notification. Accomplishments for FY 1987 include:

- Provided $25 million to 55 State and local health departments to support:
  - 1,100 testing sites.
  - 520,000 HIV tests, of which 31,600 (6%) were positive.
  - 968,000 individual counseling sessions.
  - 27 State and local partner notification programs.

## General Information and Education

CDC began a comprehensive information/education program in October 1987 with AIDS Awareness and Prevention Month. Accomplishments for FY 1987 include:

- Multi-Media Advertising Campaign, "America Responds to AIDS."
- National AIDS Hotline.
- National Clearinghouse.
- Health Worker Education.
- Provided funds to 59 State and local health agencies for AIDS information/education programs.

## School and College Age Youth

CDC is making special efforts to introduce AIDS education into school health curricula. Highlights for FY 1987 include:

- Developed "Guidelines for Effective School Health Education to Prevent the Spread of AIDS."
- Funded 15 State and 12 local education agencies.
- Established training and demonstration centers in 2 States and 1 city.
- Provided funding to national organizations to assist schools across the nation in delivering effective AIDS education, particularly to minority youth and those not in school.

## Minority Focus

Black and Hispanic populations are only 18 percent of the U.S. population but account for over 38 percent of AIDS patients. Of pediatric AIDS cases, 76 percent are Black or Hispanic. CDC is developing specific initiatives for minorities. Highlights for FY 1987 include:

- Funds were provided to 41 State and local health programs for prevention of AIDS among minorities.
- 1,140 people attended the First National AIDS Minorities Conference, held in Atlanta in August 1987.
- Funds were provided to Black and Hispanic advertising agencies and production firms as a part of the "America Responds to AIDS" advertising campaign.
- Funds were awarded to minority community-based organizations to support an AIDS information/education program through the U.S. Conference of Mayors.

## OTHER INFECTIOUS DISEASES

## Sexually Transmitted Diseases (STD)

There were nearly 14 million cases of STD in FY 1987, mostly occurring in adolescents and young adults. Etiologic studies in both Africa and the United States in heterosexual and homosexual populations have shown a strong association between genital ulcer diseases (syphilis, chancroid, and herpes) and HIV infection.

Infectious syphilis has increased by 25% nationwide to about 34,000 cases but is approaching increases of 100-150% in the same areas with high HIV prevalence. These increases are appearing in minority, inner city, hetero-sexual minority populations--the same groups that are at high risk of HIV infection.

Chlamydia is estimated to cause 4 million acute infections annually. Its annual costs are estimated to be at least $1.4 billion. Currently, 37 States have at least one city or county STD program that offers comprehensive surveillance, diagnostic testing, and treatment service for chlamydia.

While CDC outreach efforts prevented almost 150,000 cases of gonorrhea and a decrease in cases occurred during 1987, strains of antibiotic resistant gonorrhea have increased to epidemic levels in a number of States. We are continuing to provide special investigative efforts and to evaluate alternative therapies.

## Immunization

There has not been a case of polio caused by wild polio virus endemic in the U.S. since 1979--that is successful prevention. We can point with pride to the fact that the 1990 Objectives for this nation in reducing cases of rubella, diphtheria, tetanus, and polio already have been achieved. Immunization levels of the approximately 3.8 million children entering school for the 1986/87 school year were the highest in history--97 percent for measles, rubella, mumps, polio, diphtheria, pertussis, and tetanus. We have not been as successful in reaching our goal of measles elimination. Further progress in reducing preventable cases will require greater efforts by parents to see that their children are immunized at the recommended age and to assure that no eligible but unimmunized children attend school.

## Tuberculosis

In 1986, 22,768 cases were reported to CDC, representing a 2.6% increase over 1985. This was the first increase in indigenous TB since national reporting began in 1953. This increase, at least in part, was due to the occurrence of TB among persons with AIDS and HIV infection. The burden for TB is being increasingly borne by minorities (62 percent in 1986) and the foreign-born (23 percent). In 1987 the provisional cases are 22,014, a decrease of 754 from 1986. Progress has been made in TB research. A genetic probe has been developed for rapid diagnosis, and new treatment regimens have resulted in the recommended length of TB treatment being shortened from 9 to 6 months, thus enhancing patient compliance. We are requesting $6,702,000, the same as was available in FY 1988, to continue to assist States in efforts to prevent and control the spread of TB.

## Emerging Disease Problems

The Center for Infectious Diseases is addressing newly recognized infections or vectors of potential public health significance. Lyme disease is newly recognized as a tick-borne bacterial infection capable of causing arthritis, neurological, and cardiac involvement. Recent outbreaks of listeriosis, manifested as meningitis and/or septicemia, have been associated with contaminated food. Chronic Fatigue Syndrome possibly associated with the Epstein Barr virus is an illness affecting an unknown number of individuals in the U.S. Aedes albopictus (Asian tiger mosquito), an established vector of dengue in Asia, was first discovered in the U.S. in 1985 and has subsequently been found in 15 States. Giardiasis has been identified as the most prevalent enteric pathogen in day-care children and cryptosporidiosis is a newly recognized cause of diarrhea in children who attend day-care centers. We are studying these newly emerging public health problems and developing intervention measures for prevention and control.

Mr. Chairman and distinguished Members of the Committee, it is difficult to reduce one year of work by 4,500 people to 11 pages. CDC is making progress in combatting the major killers of our time. Much remains to be done. With your support, we will continue to provide leadership in the compelling battle to prevent disease and disability and to foster good health and improved quality of life for all Americans.

I will be pleased to answer your questions.

## BIOGRAPHY OF JAMES O. MASON

| | | |
|---|---|---|
| POSITION | : | Director, Centers for Disease Control |
| BIRTHPLACE AND DATE | : | Salt Lake City, Utah, June 19, 1930 |
| EDUCATION | : | B.A. – 1954, University of Utah, Salt Lake City, Utah<br>M.D. – 1958, University of Utah, Salt Lake City, Utah<br>M.P.H. – 1963, Harvard School of Public Health, Boston, Massachusetts<br>Dr.P.H.– 1967, Harvard School of Public Health, Boston, Massachusetts<br>Internship, 1958-1959, Johns Hopkins Hospital, Baltimore, Md.<br>Residency, Internal Medicine, 1961-1962, Peter Bent Brigham Hospital, Harvard Medical Service, Boston, Massachusetts |
| EXPERIENCE | : | |
| 1983-Present | : | Director, Centers for Disease Control |
| 1983-Present | : | Administrator, Agency for Toxic Substances and Disease Registry |
| 1985 | : | Acting Assistant Secretary for Health, Department of Health and Human Services |
| 1979-1983 | : | Executive Director, Utah Department of Health |
| 1978-1979 | : | Associate Professor and Chairman, Division of Community Medicine, Department of Family and Community Medicine, University of Utah College of Medicine |
| 1976-1978 | : | Deputy Director of Health, Utah Division of Health |
| 1970-1976 | : | Commissioner, Health Services Corporation, The Church of Jesus Christ of Latter-day Saints |
| 1969-1970 | : | Deputy Director, Centers for Disease Control (CDC), DHEW, Atlanta, Georgia |
| 1968-1969 | : | Chief, Infectious Diseases, Latter-day Saints Hospital and Assistant Professor, Department of Medicine and Preventive Medicine, University of Utah, College of Medicine |
| 1964-1968 | : | Deputy Director, Bureau of Laboratories, Centers for Disease Control (CDC) DHEW, Atlanta, Georgia |
| 1961 | : | Chief, Surveillance Section, Epidemiology Branch, Center for Disease Control (CDC), DHEW, Atlanta, Georgia |
| 1960 | : | Chief, Hepatitis Surveillance Unit, Epidemiology Branch, CDC, Atlanta, Georgia |
| 1959 | : | Chief, Epidemic Intelligence Service, CDC, Atlanta, Georgia |

TEACHING APPOINTMENTS : Clinical Professor, Department of Family and Community Medicine, University of Utah College of Medicine, May 1, 1979 to December, 1983

Clinical Professor, Department of Pathology, University of Utah College of Medicine, May, 1980 to December, 1983

Clinical Professor of Community Health, Emory University School of Medicine, October, 1984 to Present

ASSOCIATION MEMBERSHIP : Chairman, Utah Governor's Advisory Committee for Comprehensive Health Planning, 1975 to 1977

Chairman, Joint Residency Committee in Preventive Medicine and Public Health University of Utah College of Medicine, 1975 to 1980 Member, Utah Cancer Registry Research Advisory Committee, 1976 to 1983

Chairman of Board, Hospital Cooperative of Utah, July, 1977 to 1979 Chairman, Utah Health Planning and Resource Development Advisory Group Executive Committee 1977 to 1979

Member, Medical Association of Atlanta, 1985 to Present

Member, Institute of Medicine of the National Academy of Sciences, July, 1985 to Present

Member, twenty-two other committees or organizations

HONORS : Alpha Epsilon Delta, University of Utah 1954

Phi Kappa Phi, University of Utah, 1956

Alpha Omega Alpha, University of Utah, 1957

Roche Award, University of Utah, 1957

Wintrobe Award, University of Utah, 1958

Delta Omega, Harvard University, 1963

Sigma XI, CDC. Atlanta, 1964

Distinguished Alumni Award, University of Utah, 1973

Beatty Award, Utah Public Health Association 1979

Administrator of the Year Award, Brigham Young University, 1980

## AIDS FUNDING

Senator CHILES. Thank you. We note that 1 year ago AIDS was 23 percent of your budget. Now it is about 37 percent of your budget.

And we note also that AIDS gets about a 31-percent increase in funding over last year's funding in your Department, and everything else gets about 2.8 percent increase.

So with all of your statement, certainly there still is a concern that AIDS is now the dog wagging the tail. And we all recognize what we have to do on that. But you have got a lot of other important functions under your house, Doctor.

And I understand that infectious syphilis increased 25 percent nationwide, however increases of 100 percent to 150 percent occurred in Florida, New York State, and Los Angeles. The same area with a high prevalence of the AIDS virus.

Studies have shown there is a strong association between genital ulcer diseases such as syphilis and the acquisition of the AIDS virus. Your budget request is essentially frozen at last year's appropriation of $65.2 million.

Is that really an adequate response to the experience that we are seeing exploding in these, at least these three States?

Dr. MASON. We are concerned about those increases, and we agree that good scientific data, particularly from central Africa, shows that genital conditions, chancroid, and syphilis, may enhance the ability of AIDS to be transmitted sexually. We need to be concerned about those very things.

I think we are just caught in the deficit problem, and it is a matter of where we are going to put the dollars that are available.

Senator CHILES. Well, last year the committee recommended one of the major factors in awarding grant money would be the incidence of the sexually transmitted diseases in each State.

We have some initial indication from Florida that that does not seem to be happening from CDC. Are you considering the incidence rate in the distribution of your grant funds?

Dr. MASON. Dr. Hinman, since you are responsible for those grants, would you like to talk about why there appeared to be a discrepancy last year?

Dr. HINMAN. The funds are not given out all at once. We make a preliminary allocation of funds, and then later in the fiscal year we complete the allocation.

It is true that comparing last year's allocation with the preliminary allocation to Florida this year, there was a decrease. I do not think this will be the case when the final allocations are made.

It is also true that Florida has had a very substantial shortage of personnel, with positions remaining vacant for a prolonged period, such that some of the funds could not have been used during the funding period.

We certainly do take incidence of disease into account as we make our grant awards.

Dr. MASON. We are noting that AIDS is not just a robber of other budgets, but it uses personnel.

I think we are seeing States increasingly having problems in staffing up, not only to meet the AIDS challenge, but often to meet other priorities. Since you only have a limited number of qualified people and you are faced with an AIDS epidemic, even though there may be money, there are not always qualified, experienced people.

That is the problem we are seeing on a national basis at the State and local level. It is going to be a real challenge to maintain all of the activities that need to be carried out if we are going to prevent disease in this country.

Senator CHILES. I note that we have some young people who have entered the room. I would just tell them that Dr. Mason is head of our Centers for Disease Control, and as such he is in charge of our fight against all diseases and vaccines, including AIDS, in the country.

And we are discussing his budget. We know there has been a large increase in the amount of money for AIDS funding, and we are looking at a number of the other areas, including immunization, vaccines, vaccination, and also other sexually transmitted diseases that we see are also growing.

I understand they are from Florida. Well, I did not know that when I was saying that. We are delighted that they are here listening.

Are we providing money for training for some of these other venereal disease clinics and problems? Or is all of that staff going off to the AIDS programs?

Dr. MASON. We are certainly not using immunization or any other money to subsidize AIDS.

But it is a robbing Peter to pay Paul, because if a State puts out an announcement for a person in AIDS, they often have to take that person from immunization. At the Federal level, due to ceilings on FTE's, we have only had a specific number of field staff available.

When we put out an announcement for someone to help with the AIDS epidemic, we are competing for our own people who are assigned in immunization, or diabetes, or any other type of control program.

With the fiscal year 1988 appropriation language, you exempted our field staff from the FTE ceiling, and that has allowed us, for the first time, to take a systematic look at needs at the local level. We can now bring people into the training system to begin meeting the Federal, State, and local health department needs for these people who are assigned in lieu of cash.

Senator CHILES. Relieving you from the personnel ceilings, the FTE has helped you in your problem.

Dr. MASON. With that exemption of field staff from the ceiling, we can plan for needs of the local and State levels, and not have to worry about what it does to our Federal FTE ceilings.

We can now approach this in a logical, reasonable way to hire and train people to be prepared, so that we can staff immunization programs at the same time we are doing STD and AIDS programs.

Senator CHILES. Again, for our young people, because I brought this up before they came in, we are asking Dr. Mason about the fact that our funding for AIDS in his budget has increased 31.4 percent.

We are exploding in the money that we are putting in for AIDS, and it is necessary, it the greatest problem that we face in the public health. But all of his other funding has increased only 2.8 percent.

And of course, that includes all of our vaccine and all of these other problems, including some very serious increases in syphilis and other venereal diseases we see.

The fiscal year 1989 request for the immunization grant program is $92.8 million, an increase of 7.7 percent over last year. But the request does not include any funds for State operation costs such as surveillance, investigation, and programs coordination. Last year we were able to provide about $9 million of these costs.

In the past the administration has proposed user fees to cover such program costs, so that the State health departments could charge patients for vaccines. Congress enacted into law a provision that prohibited this from happening.

If the Federal Government does not help, how are the States going to cover these program costs?

Dr. MASON. To enable the Federal Government to provide the same number of doses of vaccine, which is approximately 50 percent of vaccine used in the Nation, we have increased funds for vaccine purchase by about $15 million to purchase the same number of doses. You are absolutely correct, in enhancing the immunization grant program to provide doses of vaccine, the amount of money available for State operations will go down to zero in fiscal year 1989.

The States are going to have to use State resources to provide for administering the vaccines, following up on vaccine reactions, and things of this nature. It will have to be done with funds from the State or local government.

Senator CHILES. Would the inclusion of the liability-related vaccine surtax and the price of vaccines, can we anticipate that the vaccine prices will now decline over a period of time, and we will not be so hard-pressed to fund these other program costs?

Dr. MASON. When we submitted our fiscal year 1989 request, we assumed there would be an increase in the cost of most vaccines, and that the tax surcharge would outweigh any other reductions.

Dr. Hinman, you are involved in the negotiations for the purchase of vaccine. Tell us what has happened.

Dr. HINMAN. What has happened is that the excise tax has been added on to the earlier cost of some vaccines, but not totally for others.

It is a fairly complicated proposition. The surtax was $4.56 a dose for DTP vaccine. The DTP vaccine manufacturers decreased the amount that they were setting aside internally for liability by about $2, and then added the surtax, resulting in a net increase in the cost of DTP vaccine of about $2.66 a dose.

For measles, mumps, and rubella vaccine [MMR], the manufacturer just tacked the $4.44 a dose surtax onto the cost of the vaccine. And for polio vaccine, the manufacturer absorbed the 29 cents a dose excise tax into their existing price.

The net effect of that was to increase the cost of vaccines in this country. The budget request for 1989 takes the excise tax into account. And in order to meet the cost of the excise tax, basically, this results in the discontinuance of projections for State operations.

In the future, we do not know what is going to happen to vaccine prices. If the compensation program works——

Senator CHILES. I guess that is my next question. And again, for the sake of our young people that are here, we have seen an explosion in the cost of vaccines as we began to see lawsuits coming in where people were paid large judgments as a result of problems.

No matter how safe we think a vaccine is, and we know they are very necessary and have helped us tremendously in fighting polio, which we have kind of eradicated, and smallpox and everything else from whooping cough on, but there are certain people that the way the vaccine is delivered or how it affects them or something else, are paralyzed or have some very bad result.

Some of those lawsuits came into play, and the judgments were so high that companies began to go up in their costs. That again made it very hard to provide the vaccine to people that can afford it.

Congress has been wrestling with this. We have set up a compensation program, you might explain that just very briefly. We try to limit those awards and the judgments, we have set up a surtax to try to say that we will put in a fund that this will be paid out of, all of which is to try to keep those vaccines from going up so high that people will not be able to afford them, or that the Federal Government will not be able to afford to provide those for people that cannot provide for themselves. But roughly go over the compensation program.

Dr. HINMAN. The idea is to establish a system which will provide relatively certain and rapid compensation for children who are damaged by vaccines which are widely recommended.

The program requires that instead of filing suit against the manufacturer, which is the way the system used to work, a claim has to be filed in the U.S. claims court. Then there is a review process in which if the child can be shown to have suffered a specific reaction, again listed in the act, there will automatically be compensation offered.

This compensation is unlimited in terms of medical care or rehabilitation expenses, and special education. There are limitations on the lost wages, and on pain and suffering.

But the process is supposed to be handled very rapidly. If the individual is not satisfied with the result of this process, he or she can decide not to accept whatever award is given, to accept the recommendation of no award, and then sue the manufacturer.

And here is where one of the problems comes up. The manufacturers believe that they are not going to see a decrease in the number of suits brought against them, because they believe that many people with very serious problems will not be satisfied with the award given by the compensation program, and will then go on and sue.

So the manufacturers are retaining their liability set-aside, and taking to some extent a wait-and-see attitude. So that is the uncertainty at the present time.

Senator Chiles. In the past 2 years, Congress has included funding for H influenza B vaccine in the childhood immunization program.

We have recently read where the Food and Drug Administration has licensed a new vaccine which has become the doctors' vaccine of choice. The new one costs five times as much as the one used by you now.

Based on the number of doses that you plan to buy, an additional $12.8 million would be required. Since you have not budgeted for this, I assume you are using the old vaccine. And why is that?

Dr. Hinman. We have not as yet completed negotiations for a contract to purchase the new Haemophilus influenza B vaccine.

Our planning for fiscal year 1989 assumed that there would be a $4.56 increase in the price of DTP vaccine; that is, that the excise tax would be added on to the total price.

In fact, the price only went up about $2.60 a dose, so there is some net savings there. And we believe that that net savings, plus what was budgeted for the older H flu vaccine, will enable us to provide the new polysaccharide vaccine for the coming year.

Senator Chiles. Does it look like the manufacturers are coming in or in your negotiations with any lower prices?

Dr. Hinman. I cannot speak to that at the present time. I do not know the response.

Senator Chiles. In the past 3 years an injury prevention program has been funded. For 1986 and 1987, the Department of Transportation got a $10 million appropriation and transferred the funds to CDC.

Last year a total of $7.9 million was appropriated, and $6.5 million in the transportation bill, and $1.4 million in our bill. Where have we made a difference in the prevention of injuries? And how do you measure this?

Dr. Mason. First, I would like to say that 140,000 people in the United States die each year as a result of injuries, and the cost to the United States is in the range of $100 billion.

We are talking about an absolutely immense problem. A lot of these injuries, whether it is in the workplace or in our homes, or carnage on our streets, those injuries are preventable. Injuries include homicide and suicide.

This Nation needs a focus to do something about preventing, rather than just treating, injuries. The Department of Transportation began providing CDC with money after the Institute of Medicine and the National Academy of Sciences published their report, "Injury in America," and recommended that there be a single focus, and that it be at CDC.

That is why the Department of Transportation transferred funds to CDC.

Senator CHILES. You are in the last year, or is next year the last year they are going——

Dr. MASON. That is right. We have put together a comprehensive plan to prevent intentional and unintentional injuries in the United States.

We have funded a series of injury prevention centers in academia, where they are putting together a critical mass of people who can concentrate and focus on what we need to do to stop this carnage, which is unnecessary.

Since this is located in academia, it also opens the door to trained specialists that can be involved, either to prevent injury or to treat injuries appropriately, so you do not get the disabilities, the preventable disabilities that could occur.

We have put out grants to a series of research groups who are specifically studying a series of areas where we can focus on reduction in the number of injuries.

The recent action that was taken to ban three-wheeled recreational injuries was a direct result of a study that we did, in this case, in Alaska, but it is applicable to the lower 48 as well.

I think this is one illustration of the many things that are being done. Manufacturers of water heaters today turn the thermostat down so that babies and older people will not be scalded. They were set so high that elderly people or mothers with babies, who were not aware, could scald themselves or their babies. We know today that the only place in the home where you need hotter water is in the automatic dishwasher.

Senator CHILES. What happens when you lose the transportation money?

Dr. MASON. Well, we are down to about $1.4 million per year, which is——

Senator CHILES. That is a lot less than $8 million, or $9 million, or $10 million.

Dr. MASON. Bare bone.

Senator CHILES. Last year the committee provided $2.4 million to close the gap between research findings and the application of these findings in clinical practice of diabetes health care.

I understand you are spending $629,000 of this money for State data systems and expanding incident studies. Is there not anything more direct that we can do to get these research findings into clinical practice?

Dr. MASON. Yes; I think we have two things going. We have the $2.3 million for translation, and then we have $4.9 million for cooperative agreements with States.

The cooperative agreements have been going on for more than 5 years, and we have already begun to see what is happening in reducing diabetic-related blindness, diabetic-related amputations, and other problems. So the $4.9 million, I think, has demonstrated what State and local health departments can do.

The translation is aimed specifically, just as you have said, to taking facts that are coming from NIH and academia, and getting them down to the practicing physician. Not just the specialist but the person in general practice, the private clinic, the public health clinic, and wherever diabetics are being seen.

Your figure of $600,000 represents what was recommended by the National Diabetes Advisory Board in its "Long-Range Plan to Combat Diabetes, 1987." We are planning to spend at least $125,000 on improving State data systems. We do not even know in this Nation the total number of preventable complications of diabetes. And so the money was appropriated to begin the process of translation, which has to start with a data base to measure whether you are having any impact.

The very question that you asked me about injury control, have we made a difference? Well, without a national data base, you never know whether translation has made a difference.

So we are in the first year of that translation process. We will establish the baseline, and then develop the plan, so that we can really begin to have an impact upon the complications of diabetes. We do not need to treat people in hospitals for problems that could be prevented by taking early action.

Senator CHILES. Well, we hope you will continue to press that in every way you can, because I know that that information is out there, and try to get it in the hands of the people that use it.

The Centers for Disease Control has been conducting a national infant mortality surveillance project for the past few years.

What types of interventions are you proposing to reduce the incidence of infant mortality? And how are these interventions translated or carried out in practice at our health clinics? What efforts are you proposing to continue to expand in fiscal year 1989?

Dr. MASON. We work very cooperatively with HRSA, that has the maternal and child health block grant. The funding we have for infant mortality is an augmentation and complementary to what they are doing.

Our specific approaches have been to make sure that we have the data base to measure to see if we are making a difference. The National Center for Health Statistics, which is now part of CDC, has been working with us to link the death certificates with the birth certificates, so that we can track children and really measure how many deaths are occurring in the United States, and specifically what are the causes of those deaths.

Again, it is getting a baseline of information and then knowing specifically what are the causes of death. I think that has been a major step forward.

In terms of specific actions we have taken, there is a major initiative in preventing the use of tobacco by women who are planning to have a baby, or women who are already pregnant.

We know that low birth weight is one of the most common causes of infant mortality, and the use of tobacco by the mother, smoking during pregnancy, is one of the significant causes of low birth weight.

We are working with the Department of Agriculture——

Senator CHILES. Do you put out information in that regard?

Dr. MASON. Yes.

Senator CHILES. Please furnish us with it.

Dr. MASON. We would be happy to.

Senator CHILES. Do you have that same information that you give in regard to alcohol and drugs, or other medicines?

Dr. MASON. Alcohol and drug information would largely come from ADAMHA. We pick up the smoking side of this.

But we would be happy to give you some, I think, beautiful material. We have public service announcements on television, we have literature that is given to women, we are working with States so that in——

Senator CHILES. What are you putting out in regard to nutrition information? Because we know again, low birth weight, and it is alcohol, tobacco, and failing to eat properly.

Dr. MASON. That is where I was going next. We have been working with the Department of Agriculture in the WIC clinics. We are encouraging women to utilize the services of the WIC clinic during their pregnancy, we are helping the Department of Agriculture in evaluation of what food to have in the WIC clinics, what to retain, and what is not needed.

For example, we just finished a survey of anemia among newborns and pregnant women. Because of that survey, the Department of Agriculture is going to continue to include iron supplement in cereals and in other foods that are available for both mothers and infants in the WIC clinics.

Our stresses in the past year have been working with the Department of Agriculture; women, infants, and children's clinics; and reducing low birth weight infants, and then getting the linkage between the——

Senator CHILES. Any nutritional information you have, I would like to see that too.

Dr. MASON. All right.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. Doctor, we will have some other questions. We will ask those for the record. We are going to have a vote right now.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## VACCINE STOCKPILE - CURRENT SUPPLY

Question. The goal of the vaccine stockpile is to have a six-month (26 weeks) supply of vaccine doses on hand in case of a manufacturer's production problem or in case of an emergency. There is not any funding for the stockpile in the fiscal year 1989 request.

What is the current supply on hand for the stockpile?

Answer. The current status of the vaccine stockpile is as follows:

CDC Vaccine Stockpile
Status 5/2/88

| Vaccine | Purchased to Date # Doses | # of Weeks | Delivered to Date # Doses | # of Weeks |
|---|---|---|---|---|
| DTP | 5,569,995 | 13.8 | 2,608,995 | 6.5 |
| OPV | 6,611,000 | 20.5 | 6,611,000 | 20.5 |
| MMR | 1,680,000 | 20.8 | 1,129,500 | 14.0 |
| IPV* | | | | |
| DT | 400,000 | 20.8 | 400,000 | 20.8 |
| Td | 4,560,000 | 20.8 | 4,560,000 | 20.8 |

*New contract being negotiated

Notes:

1. The actual number of doses of DTP currently in storage is 2,494,995. This is due to a partial drawdown of the delivered stockpile by Connaught in January 1987, which has not been entirely replaced to date. This drawdown was approved by CDC to prevent shortages of DTP in the national delivery system due to production problems.

2. The actual number of doses of MMR currently in storage is 996,685. This is due to a partial drawdown of the delivered stockpile by Merck Sharp and Dohme in November 1986, which has not been totally replaced to date. This drawdown was approved by CDC to prevent shortages of MMR in the national delivery system due to production problems.

3. It is projected that an additional 634,500 doses of DTP vaccine and 19,180 doses of IPV will be added to the stockpile with appropriated funds in FY 1988.

Question. What is the cost of the vaccine needed to complete the stockpile?

Answer. The cost of vaccine needed to complete the stockpile depends on whether or not vaccine which is purchased for the stockpile remains subject to the excise tax. If payment of excise tax is required, it would cost an estimated $35,246,007 to complete the stockpile. If the excise tax is waived for vaccine which is purchased for the stockpile, the cost would be reduced to an estimated $10,288,137.

These estimates include completing a six-month stockpile supply for those childhood vaccines (DTP, OPV, MMR, IPV, DT Td) for which stockpile purchases have previously been initiated. However, completing the stockpile in one year would not be feasible since the vaccine manufacturers cannot increase their production fast enough to accommodate such a large order for all vaccines.

Question. In your opinion, how much supply on hand is required to prevent any unforeseen drop in supply?

Answer. When we developed the criteria for the stockpile, we determined that a stockpile which would last six months was the ideal size. We still believe this is the appropriate size. If manufacturing problems arise, six months is usually required to manufacture a vaccine from start to finish. With anything less, we may risk running out of vaccine before the manufacturing plants can again begin production. With a larger stockpile, the manufacturers have problems in rotating the stockpile to ensure that the vaccine has proper dating.

## AIDS FUNDING - IMPACT

Question Dr. Mason, as I review the funding requirements of your budget, I can't help but notice that $401 million of your total $924 million fiscal year 1989 request is for AIDS-related activities. That represents 43 percent of this year's budget. Last year, AIDS-related activities represented 37 percent of your budget, and two years ago, AIDS-related activities represented 23 percent of your budget.

Yet, the Centers for Disease Control (CDC) has other important program areas, such as: the childhood immunization program, the sexually transmitted disease program, chronic and environmental disease prevention program, and so on.

My question to you is this: The funding for these several important areas has remained level. Are you satisfied, particularly in light of the increase that has been provided for AIDS activities, that other CDC program are adequately funded?

Answer. The funding offsets required to support the large increase in CDC's AIDS activities within the Bipartisan Budget

Agreement for 1989 are generally not coming at the expense of non-AIDS programs in CDC. Almost all of CDC's non-AIDS activities are at least maintained in 1989 at the 1988 level. Throughout PHS, non-AIDS funding is increased by 5.4 percent in 1989 over 1988. Of course, there are always more opportunities for program expansions in all areas than resources to support them. Within the funds available, CDC is supporting those projects which it believes are the highest priority. For any further program increases beyond those included in the FY 1989 President's budget, no further offsets have been identified which would be required to remain within the ceilings of the Bipartisan Budget Agreement.

## NATIONAL VACCINE PROGRAM

Question. Dr. Mason, I understand that you have new program responsibilities related to the vaccine injury compensation program. For example, health care providers must report to you, the Centers for Disease Control (CDC), certain adverse effects from vaccines purchased with public money. Those record-keeping costs are estimated to be $2 million for next year. In addition, the authorizing legislation requires you to conduct several studies on vaccine development and safety. Those costs are projected to be about $8 million.

Your budget request includes $500,000 for administering the national vaccine program. How will you be able to administer your new program responsibilities with that level of funding?

Answer. The budget request for CDC includes $500,000 for the Coordinating Office for the National Vaccine Program. This request is sufficient to conduct the activities of that office. Estimates for implementing various activities and requirements of the Compensation Program were not available at the time the 1989 budget was developed to remain within the ceilings established by the Bipartisan Budget Agreement, and no offsets have been identified to accommodate additional activities and still remain within the budget ceilings. Should any additional costs be shown to be required, these can be dealt with in the context of future budget requests.

## TUBERCULOSIS ELIMINATION

Question. Dr. Mason, we understand that the incidence of tuberculosis is on the rise again, and that CDC has recently developed a comprehensive strategic plan for the elimination of tuberculosis in the United States. I understand your tuberculosis plan would cost $28.5 million in 1989 but you have only requested $6.7 million. Why is that?

Answer. From 1985 through 1987, over 67,000 cases of tuberculosis were reported-about 10,000 more than expected based on the observed trend from 1981 through 1984. The failure of tuberculosis to decline recently can be attributed primarily to an increase in TB occurring in persons with HIV infection.

Other major current problems are TB occurring among racial and ethnic minorities (62 percent in 1986); among the elderly (29 percent in 1986); and among the foreign-born (23 percent in 1986). Tuberculosis disease and infection is concentrated in identifiable geographic areas and populations groups which are amenable to intensified prevention and control efforts. An estimated $536 million are spent annually for tuberculosis control. Most of these costs are borne by State and local governments.

The $6 million for FY 1989 in CDC's budget represents a continuation of the FY 1988 appropriated level for the tuberculosis cooperative agreement funding used mainly to hire outreach workers who provide directly observed therapy to patients who would otherwise not complete the treatment needed to cure them and make sure they do not spread their disease.

Many health departments report that for every cooperative agreement dollar spent for observed therapy, an estimated 3 to 4 dollars in hospitalization costs are saved. Nationally, this could represent a savings of $21-$28 million each year. It should also be noted, though, that we expect the major efforts we are expending to solve the problems of substance abuse and AIDS should have a significant impact on decreasing the incidence of tuberculosis.

A departmental Advisory Committee for Elimination of Tuberculosis (which includes TB experts, PHS agencies, and constituency groups) was recently formed. This committee, in conjunction with our Division of Tuberculosis Control, is finalizing "A Strategic Plan for the Elimination of Tuberculosis from the United States." This plan anticipates the elimination of TB by the year 2010 with an interim target of a case rate of 3.5/100,000 by the Year 2000. Although the plan is not yet finalized, many of the steps needed for elimination of TB are known and CDC, NIH, and the States have begun their implementation. For example, CDC continues to work with the States, professional societies, and voluntary organizations to ensure more cost-effective programs and better use of existing technology. We are continuing our operational research activities to develop and assess better methods of diagnosis, treatment, and prevention.

## NATIONAL PLAN FOR PREVENTION OF DISABILITIES

Question. Briefly, what methods of prevention do we use to decrease the incidence of disabilities?

Answer. First, CDC defines a disability as a health condition which interferes with a person's normal activities. We have targeted three types of disabilities: developmental disabilities (mental retardation), injuries (head and spinal cord), and secondary disabilities (complications of existing physical disabilities).

Examples of causes of head and spinal cord injuries and the methods being used to prevent those injuries are: motor vehicles (use of seat belts, use of airbags, control of alcohol abuse); intentional injuries (control of the use of guns, alcohol, and drugs); sports injuries (safer playgrounds, improved water safety, improved athletic equipment).

Examples of the causes of developmental disabilities and the methods being used to prevent them are: PKU, congenital hypothroidism (newborn screening); congenital rubella, measles, Rh hemolytic disease, Hemophilus influenza meningitis (immunizations); low birth weight/prematurity, malnutrition, maternal chronic disease (prenatal care); AIDS, Down syndrome, spina bifida, maternal chronic diseases, selected other genetic disorders, fetal alcohol syndrome (preconception counseling and/or prenatal diagnosis); lead poisoning, injury and poisoning, socio-cultrual deprivation (modification of cultural environment).

For the prevention of secondary complications of primary disabilities (e.g., paraplegic becoming a quadriplegic) CDC is seeking to identify the most effective means of prevention.

Question. I understand that about ten States will be awarded grants to administer this program. How will the States use this money?

Answer. CDC plans to make awards through cooperative agreements to ten States. In all ten States, the funds will be used to build technical assistance and planning capacity for the prevention of targeted disabilities. In approximately five of the States, the funds will support the implementation and evaluation of community projects to prevent targeted disabilities.

## PREVENTIVE HEALTH SERVICES BLOCK GRANT

Question. Dr. Mason, the Preventive Health Services Block Grant has been level funded or cut for the past several years. How has that affected the States' programs?

Answer. These block funds are used to supplement State programs; when the funds are reduced, the States respond by substituting other State funds or by reducing activities, keeping in mind their priorities and needs. For example, a realignment of priorities in some States has resulted in a reduction of the support for rodent control. Since the block grant funds support many different programs at varying degrees across the country, it is difficult to analyze the overall program significance of a reduction in funds, but no apparent program deteriorations have been reported.

## TUBERCULOSIS CONTROL TECHNIQUES

Question. Late last year, Congress enacted a bill that substantially increases the authorized level of funding for the TB grant program, and also established a research and demonstration authority to study and test new TB control techniques.

If Congress substantially increased the level of funding for the TB program, how would CDC utilize these resources to carry out the strategic plan to eliminate TB?

There are always more opportunities for program expansions than resources to support them. Within the resources available to CDC, the highest priority projects are being funded. For any additional projects, however, we have not identified offsets within the budget request which would be required to remain within the ceilings of the Bipartisan Budget Agreement for FY 1989. If additional funds for TB projects become available, CDC would seek to help the States more rigorously implement the "Strategic Plan for the Elimination of tuberculosis from the U.S."

A tuberculosis patient must take medications for 6 to 18 months to be rendered noninfectious and cured of disease. Patient noncompliance is a major problem with these long-term treatment regimens. The current tuberculosis cooperative agreement funds are used mainly to hire outreach workers who provide directly-observed therapy to noncompliant patients who would otherwise not complete treatment. Many health departments estimate that for every dollar spent on directly-observed therapy, 3 to 4 dollars in hospitalization costs are saved. If additional resources were available, they would be used in part to expand the tuberculosis cooperative agreement program to all States and cities with a high incidence of tuberculosis and increase the proportion of patients receiving directly-observed therapy. Additional resources would also allow the assignment of a few physicians to work in high incidence areas and to assist with local elimination efforts. This is necessary because in many areas physicians with expertise in tuberculosis are unavailable.

Furthermore, tuberculosis disease and infection is becoming concentrated in identifiable geographic areas and population groups in which tuberculosis is amenable to intensified prevention and control efforts. Additional resources would allow the initiation and expansion of tuberculosis screening and prevention programs targeted to high-risk groups, especially minorities, the elderly, and the foreign-born.

Additional funds would also be used to expand research activities, particularly to develop new treatment and preventive treatment regimens, new diagnostic tools, and effective vaccine(s) needed to eliminate tuberculosis.

## VACCINE INJURY COMPENSATION LAW

Question. I understand that the vaccine injury compensation law requires that recipients of vaccines, including parents and guardians, receive information about the vaccines with which they have been inoculated.

How much do you estimate State and local governments will require to produce and distribute these information pamphlets?

Answer. Section 2126 of the National Vaccine Injury Compensation Program mandates that the Secretary shall develop and disseminate vaccine information materials for distribution by health care providers to the legal representatives of any child receiving a vaccine set forth in the Vaccine Injury Program. It is anticipated that three separate forms will be developed--one each for DTP and its components, MMR and its components, and polio vaccines.

These will be provided in camera-ready forms to State health departments, who will add to them the State-specific information required, print them, and distribute them to all vaccine providers, both public and private, within their State. These forms will be printed in English, Spanish, French, Chinese, and Vietnamese. The annual cost to the States to carry out this activity for both public and private health care providers is estimated to be $6,086,000.

## TIMELINESS OF THE RELEASE OF NCHS DATA

Question. This year, the budget request for the National Center for Health Statistics falls under the jurisdiction of the Centers for Disease Control.

We have heard complaints in the past that some of your national surveys and publications are not completed within the regular time period. Why has this happened?

Answer. Timeliness of data has been a problem for NCHS. NCHS has recognized timeliness as a priority concern and has made considerable progress in reducing the time between data collection and release. Efforts contributing to this improvement include:

o Automated publishing. Last year, NCHS began to utilize this technology to increase the efficiency of producing and disseminating published reports. Now, many of the Center reports are produced electronically. This decreases the time spent in the production cycles and many reports now have a far faster turnaround from data analysis to dissemination.

- The automation of data collection is an integral aspect of upcoming surveys, such as the National Health and Nutrition Examination Survey, Cycle III. This six-year survey program expects newly-installed automated systems to reduce data collection and processing time and, thus, produce data considerably ahead of the schedule for previous surveys.

- Many data users rely upon the public use data tapes for access to NCHS data. Improvements in the timeliness of data tape release have been implemented. For example, the National Health Interview Survey now releases the final public use data tapes 11 months after the end of data collection. Preliminary files are available earlier to collaborating agencies.

- The special survey on AIDS Knowledge and Attitudes provides another example for data collected, processed, and released in a very timely manner. The first publication appeared three months after data collection began.

## NCHS - FY 1989 FUNDING REQUIREMENT

Question. The fiscal year 1989 budget request totals $61,424,000, of which $12,486,000 shall be derived from the set-aside for evaluation funds. If funds were not available from the individual evaluation set aside, what amount of funding would be required to maintain your programs on a level operating plan?

Answer. A total of $61,424,000 in new budget authority would be required to maintain NCHS survey operations at the level of their current operating plan if funds from the PHS-wide 1 percent evaluation fund were not available to help finance some of NCHS's national surveys.

## EDUCATIONAL RESOURCE CENTERS FUNDING

Question. The Educational Resource Centers were established to expand university programs in the occupational health field. The fiscal year 1989 request is $6,600,000, a reduction of $3,118,000, or 32 percent, from last year's appropriation of $9,718,000. Other than the vaccine stockpile, this is the only cut requested in your budget. Why are you proposing this cut?

Answer. The President's FY 1989 budget assumes that these activities will be supported progressively from non-Federal funding sources. Full funding from non-Federal sources is projected by FY 1991. Nine of the existing 15 university-based Educational Resource Centers (ERCs) have had federal developmental support for 10 or more years. Federal support for these programs of academic and continuing education training has served its original purpose of developing educational curriculum and increasing student, business, and public health interest in the occupational safety and health field. The ERCs should now be able to continue these programs without this Federal institutional aid.

Question. What evidence suggest that these universities can develop alternate sources of funding?

Answer. Currently, the ERCs receive approximately 25 percent of their funding from other sources. Two California ERCs have supplementary State funding. The Washington ERC receives some funding from the Statewide workers compensation funding pool. Some of the State-funded universities with ERCs have increased faculty support. The ERCs have begun discussions with other potential non-federal funding groups. The American Industrial Hygiene Foundation (AIHC) has developed a trust fund to provide some scholarships and grants to individual students. These funds include donations from corporations and individual donations from AIHA members. Also, the American Occupational Medical Association is exploring the feasibility of private funding sources for occupational-medical residency programs.

## HAZARDOUS RISKS IN THE WORKPLACE

Question. As you know, the Congress has considered S. 79, the High Risk Occupational Disease Notification and Prevention Act. This legislation would direct the Centers for Disease Control (CDC) to identify, notify, and monitor workers whose health is at risk from exposure to hazardous substances in the workplace. Under this legislation, how many individual workers would be notified each year about hazardous risks in the workplace?

Answer. The legislation provides a target of 100,000 to 300,000 workers to be notified per year.

Question. What do you estimate the cost is to notify each worker?

Answer. It is estimated that the notification cost is $33.00 per worker notified. Therefore, the costs of notifying 100,000 - 300,000 workers per year would be $3.3 - $9.9 million.

Question. The bill authorizes $25 million for the Centers for Disease Control (CDC) to administer this program. Do you think that is an adequate funding level for this program?

Answer. The funding level of $25 million would be an adequate level to carry out the requirements of the bill, including notifying at least 100,000 workers per year and funding 10 medical centers. In FY 1988, CDC/NIOSH is evaluating five previously completed mortality studies to determine whether surviving subjects of these studies should not be notified individually of the results. The criteria for this evaluation are the guidelines established in 1986 by the NIOSH Board of

Scientific Counselors, and NIOSH expects to conduct one major worker notification effort during FY 1988.

CDC's FY 1989 budget request includes at least $200,000 for CDC to continue the current services level and evaluate five additional mortality studies and do a second major notification. Resources for additional activities beyond these efforts are not included in the budget request under the Bipartisan Budget Agreement. No offsets have been identified which would be necessary to accommodate such increases within the ceilings established by the Budget Agreement for FY 1989.

## SEXUALLY TRANSMITTED DISEASES PATTERN

Question. What has been the pattern in the incidence of the major sexually transmitted diseases over the past ten years?

Answer. During the last decade, the field of STD has evolved from one concerned primarily with the traditional venereal diseases of syphilis and gonorrhea, to one also concerned with the emerging "new" STD such as chlamydia, genital herpes, and human papillomavirus, to one preoccupied with the prevention of the human immunodeficiency virus (HIV). In addition, the recognition of the importance of the syndromes caused by sexually transmitted organisms (pelvic inflammatory disease, infertility, ectopic pregnancy, neoplasias, immune deficiencies) has been a major concern of the STD field. Ten-year figures for several of the major STD follow:

| Year | Genital Herpes[1] | Genital Warts[1] | Syphilis[2] | Primary Secondary2 Gonorrhea | AIDS[3] |
|---|---|---|---|---|---|
| 1978 | 254,530 | 1,195,937 | 21,656 | 1,013,436 | -0- |
| 1979 | 275,240 | 905,131 | 24,874 | 1,004,058 | -0- |
| 1980 | 220,581 | 985,545 | 27,204 | 1,004,029 | -0- |
| 1981 | 311,503 | 998,326 | 31,266 | 990,864 | 170 |
| 1982 | 377,155 | 1,073,031 | 33,613 | 960,633 | 1,023 |
| 1983 | 422,561 | 1,148,843 | 32,698 | 900,435 | 2,845 |
| 1984 | 450,568 | 1,148,579 | 28,607 | 878,556 | 5,757 |
| 1985 | 460,268 | 1,316,389 | 27,131 | 911,419 | 10,380 |
| 1986 | 433,212 | 1,379,673 | 27,667 | 892,229 | 16,022 |
| 1987 | 440,094 | 1,857,945 | 35,147 | 780,905 | 20,766 |

[1] Source: NDTI-includes only visits to private physician's offices

[2] Source: CDC 73.688

[3] Source: AIDS Weekly Surveillance Report, CDC

Question. Has the incidence of such diseases as gonorrhea, syphilis, chlamydia, and genital herpes increased or decreased?

Answer. Because of Federal, State, and local prevention efforts, the incidence of gonorrhea has decreased over the last decade; unfortunately the percentage of gonorrhea resistant to penicillin has increased. Moreover, syphilis, chlamydia, and genital herpes have increased over the past decade.

## CHLAMYDIA REPORTING REQUIREMENTS

Question. How many States require that chlamydia be a reportable disease?

Answer. In FY 1987, 28 States either required that chlamydia be a reportable disease, or had legislation pending to this regard.

Question. How does this compare with last year?

Answer. In FY 1986, 19 States had similar laws, or legislation pending, regarding chlamydia reportability.

Question. What is CDC's role in encouraging States to make chlamydia a reportable disease?

Answer. In CDC's 1985 Guidelines for Chlamydia Prevention, CDC recommended that all States make chlamydia a reportable disease. CDC has continued to work closely with all 50 States to provide model legislation and justification to assist them in this effort.

## STD AND INFERTILITY

Question. How many women do you estimate will become infertile as a result of sexually transmitted diseases in the coming year?

Answer. Based on our estimates of the incidence of chlamydia and gonorrhea in reproductive age women, CDC estimates that 125,000 women will become infertile because of STD in 1988.

Question. What types of activities does CDC support to disseminate information about the relationship of sexually transmitted diseases and infertility to the attention of women in this Nation?

Answer. CDC supports a wide variety of public information activities to educate the American public--and especially reproductive age women--about the importance of STD in the etiology of infertility. Over the past year, CDC has worked with States to provide basic information for the media, the schools, and private organizations to emphasis this role. In addition, CDC has encouraged States to use the concept of a "reproductive life plan" which helps young individuals today recognize that the STD they acquire now may have adverse effects on their ability to reproduce in the future.

### PREVENTIVE HEALTH BLOCK GRANTS - EMERGENCY MEDICAL SERVICES IN RURAL AREAS

Question. We hear a lot about the problems of providing emergency medical services in rural areas around the country. What role, if any, does the Preventive Health Block Grant play in supporting rural emergency medical services? Are any States using allocations from this block grant to improve rural emergency care? Please provide examples.

Answer. Yes, the Preventive Health Block Grant is used in the support of rural emergency medical services. Consistent with the present law, such services include planning, feasibility studies, training of emergency medical service personnel, etc., since support of emergency medical service operations and purchase of equipment is not allowed. Examples of States using the funds for rural emergency medical service activities are West Virginia, Colorado, and Idaho.

## QUESTIONS SUBMITTED BY SENATOR ROBERT C. BYRD

### NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

Question. Two divisions of the National Institute for Occupational Safety and Health are located in Morgantown, West Virginia. That facility is of primary importance to the research being done on respiratory diseases of coal miners, and, as you know, is the national depository for x-rays of those suffering from black lung disease.

Would you provide me with the number of support and scientific personnel and research projects and the dollar amounts associated with those activities at the Appalachian Laboratory on Occupational Safety and Health for fiscal year 1987, fiscal year 1988, and what is projected for fiscal year 1989? Please include in that same report, any research or other activities that will be terminated or delayed in fiscal year 1989.

Answer.

APPALACHIAN LABORATORY ON OCCUPATIONAL SAFETY AND HEALTH
($000)

| FY 1987 ACTUAL | | FY 1988 ESTIMATE | | FY 1989 ESTIMATE | |
|---|---|---|---|---|---|
| FTEs | BUDGET | FTEs | BUDGET | FTEs | BUDGET |
| 222 | $13,087 | 237 | $13,780 | 237 | $13,780 |

The funds expended or estimated above include research projects, projects in support of research activities, and administrative support costs.

At the present time, we do not anticipate any current research or other activities to be terminated or delayed in FY 1989.

Question. The report accompanying the FY 1988 appropriation bill provided $700,000 for research at the Division of Respiratory Disease Research. Please provide a report on the status of that funding, together with a break out of the number of staff hired and equipment purchased.

Answer. In response to this question, we will submit the report as directed by the appropriation language, which is as follows. "The Committee urges NIOSH, within available research resources, to provide $700,000 for occupational safety and health research for the coal miners pathology and autopsy program, research on medical surveillance of coalworkers pneumoconiosis, silicosis eradication, and epidemiological studies of surface coal miners, welders, and diesel-exposed miners, and expansion of the National Occupational Health Survey of Miners. The Committee is concerned over reports of reduced research efforts in the area of occupational respiratory diseases and reports of vacancies that have not been filled. Therefore, the Committee directs that a report be submitted to the Committee no later than June 30, 1988, detailing research undertaken and the dollars associated with that research by object class." This report is a listing of those DRDS research projects within these specific areas, research activities undertaken, and funding allocated in FY 1988 by object classification.

NIOSH is presently recruiting for a pathologist and histopathologist technician.

A listing of equipment purchases has been included for each project.

DOLLARS ASSOCIATED WITH ALL RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $31,400 | 21 |
| FOREIGN TRAVEL | 2,500 | 21 |
| NEGOTIATED CONTRACTS | 117,625 | 25 |
| OTHER SERVICES | 12,615 | 25 |
| ADP EQUIPMENT | 26,000 | 31 |
| ALL OTHER EQUIPMENT | 10,750 | 31 |
| SUPPLIES | 52,278 | 26 |
| PRINTING | 300 | 24 |
| RENT, COMMUNICATION, UTILITIES | 1,400 | 23 |
| TRANSPORTATION OF THINGS | 4,550 | 22 |
| PERSONNEL COSTS AND BENEFITS | 415,917 | 11 & 12 |
| TOTAL | $675,335 | |

DEFENSE MECHANISMS OF ALVEOLAR PNEUMOCYTES AGAINST OCCUPATIONAL AGENTS

RESEARCH UNDERTAKEN:

This laboratory based project will focus upon two important types of lung cells - the alveolar Type II cell which helps form the walls of the air sacs, and the alveolar macrophage which moves about the lung engulfing microbes and foreign materials. The primary object of this study is to learn what role these cells play in the production of a naturally produced antiviral agent called "interferon" and to what extent, if any, exposure to various occupational agents such as diesel particulates or silica interrupts or lessens the protective or beneficial health effects of this substance. Results of this study will assist the Institute in the prediction of possible health effects due to exposures of workers to various occupational agents.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| FOREIGN TRAVEL | $2,500 | 21 |
| OTHER SERVICES | 8,545 | 25 |
| ALL OTHER EQUIPMENT | 1,000 | 31 |
| SUPPLIES | 7,589 | 26 |
| PRINTING | 300 | 24 |
| PERSONNEL COSTS AND BENEFITS | 92,574 | 11 & 12 |
| TOTAL | $112,508 | |

The foreign travel planned will further collaborative research efforts with the People's Republic of China in this project of mutual interest.

## SILICOSIS: DISEASE MECHANISMS

RESEARCH UNDERTAKEN:

The goal of this laboratory based project is to provide basic information about hazardous silica dust exposures in order to both control and eliminate this dangerous work related health hazard. Animals will be exposed to silica by direct injection into the airways and/or inhalation, and the effects upon lung function and lung tissue will be measured. This data regarding the cause and effect relationship between silica dust exposure and lung disease will provide information regarding the types and levels of exposures that should be eliminated in preventing silicosis.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $3,000 | 21 |
| OTHER SERVICES | 3,270 | 25 |
| SUPPLIES | 9,389 | 26 |
| PERSONNEL COSTS AND BENEFITS | 105,800 | 11 & 12 |
| TOTAL | $121,459 | |

## ENDOTOXINS AND COTTON

RESEARCH UNDERTAKEN:

This laboratory based study is designed to investigate a variety of commercially produced and environmentally related substances called "endotoxins." These substances are principally derived from the cell walls of a specific type of bacteria technically identified as gram negative organisms. When inhaled with other materials such as cotton dust and lint, these cell wall fragments are directly toxic to the lung.

Tests will be performed to quantify a variety of commercial and environmental endotoxins, to determine optimum methods for the extraction of endotoxin from environmental dusts, and to determine the effects of endotoxin on human and animal immune systems. The information obtained will serve to identify the more toxic endotoxins so that standards development and exposure intervention techniques might follow.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $3,000 | 21 |
| NEGOTIATED CONTRACTS | 30,625 | 25 |
| ALL OTHER EQUIPMENT | 8,000 | 31 |
| SUPPLIES | 29,000 | 26 |
| PERSONNEL COSTS AND BENEFITS | 4,375 | 11 & 12 |
| TOTAL | $75,000 | |

| EQUIPMENT PURCHASED: | BUDGET |
|---|---|
| Refrigerated Centrifuge | $4,784 |
| Coulter Cell Counter and Printer | 8,910 |
| Environmental (Incubator) Shaker | 2,053 |
| Polaroid Photomicrography Equipment | 997 |
| High - Low Temperature Incubator | 7,001 |
| | $23,745 |

NCWAS: DATA ANALYSIS AND RELATED RESEARCH

RESEARCH UNDERTAKEN:

This project will assess the accuracy and the adequacy of the review of pathology specimens submitted through the National Coal Workers' Autopsy Study (NCWAS), and will then compare these findings with actual radiographic interpretations for the same individuals. In FY 1988, the project will be initiated through the selection of a pathologist and a histopathology technician, and initiation of the review of the NCWAS autopsy specimens collected from 1971 through 1980. At this time, the Institute is reserving $140,000 for release to this project upon selection and placement of the pathologist.

NHANES III SUPPORT

RESEARCH UNDERTAKEN:

This project involves the National Health and Nutrition Examination Survey (NHANES III), conducted jointly by the National Institute for Occupational Safety and Health (NIOSH) and the National Center for Health Statistics (NCHS). NHANES III is designed to provide an estimate of the occupational health of the workers in the United States.

NIOSH personnel are involved with the writing of questionnaires for the survey, maintenance of equipment used to measure respiratory function, the training of field technicians in the use of this equipment, quality control of the measurements taken, and the analysis of data collected.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $4,000 | 21 |
| SUPPLIES | 2,000 | 26 |
| PERSONNEL COSTS AND BENEFITS | 35,000 | 11 & 12 |
| TOTAL | $41,000 | |

STATE-BASED SURVEILLANCE: MEDICAL TECHNICAL SUPPORT

RESEARCH UNDERTAKEN:

This project provides medical technical support to states in developing programs for surveillance of silica-induced and other ocupationally-related lung diseases. This includes attending National Institute for Occupational Safety and Health (NIOSH) surveillance coordinating meetings and meeting with States to monitor progress on cooperative agreements with NIOSH. Activities include development of procedures to be used by State agencies for surveillance studies. In addition, this project assists States in preparation of articles describing the results of their surveys.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $5,500 | 21 |
| SUPPLIES | 2,000 | 26 |
| PERSONNEL COSTS AND BENEFITS | 46,411 | 11 & 12 |
| TOTAL | $53,911 | |

PNEUMOCONIOSIS X-RAY INTERPRETATION USING COMPUTED IMAGE MODIFICATION

RESEARCH UNDERTAKEN:

Chest X-rays are a key screening test for detection of the diseases of the lungs due to dust exposures. Certified experts ("B-readers") typically interpret chest X-rays for evidence of these diseases using a standard system developed by the International Labour Office (ILO). Nevertheless, variations in subjective interpretation of any given chest

X-ray are common. This is especially true in borderline cases. Thus, disease detection might be improved if a computerized system could be developed to measure and quantitate chest X-rays.

This project uses computerized enhancement to create consistent visual images before the interpretation of X-rays using the ILO classification system. A pilot study will provide experience in the use and teaching of the system, and define areas for further evaluation. A larger study using 300 films with three X-ray readers will then be performed. Results will evaluate the usefulness of this system in the detection of lung disease, and potentially may provide beginnings for development of a computerized system for chest X-ray interpretation as well as compact data storage and retrieval.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $800 | 21 |
| OTHER SERVICES | 800 | 25 |
| ALL OTHER EQUIPMENT | 200 | 31 |
| SUPPLIES | 300 | 26 |
| TRANSPORTATION OF THINGS | 100 | 22 |
| PERSONNEL COSTS AND BENEFITS | 39,286 | 11 & 12 |
| TOTAL | $41,486 | |

## SILICOSIS SURVEILLANCE: MORTALITY AND MORBIDITY TRENDS

RESEARCH UNDERTAKEN:

Scant information is currently available on national trends in death and disfunction related to silica exposure. This project will explore untapped, existing data sources such as the National Center for Health Statistics (NCHS) multiple cause of death listings from 1964 - 1984. Trends will be analyzed by year and state. Rates of silica-induced disease and years of potential life lost due to silica exposure will be calculated.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $600 | 21 |
| NEGOTIATED CONTRACTS | 8,200 | 25 |
| ADP EQUIPMENT | 8,000 | 31 |
| SUPPLIES | 1,000 | 26 |
| PERSONNEL COSTS AND BENEFITS | 8,730 | 11 & 12 |
| TOTAL | $26,530 | |

NATIONAL OCCUPATIONAL HEALTH SURVEY OF MINING (ENHANCED)

RESEARCH UNDERTAKEN:

The National Occupational Health Survey of Mining (NOHSM) is a long-term surveillance effort designed to collect and disseminate data on the mining workforce and their potential exposures to fibers, silica, asbestos and various chemical agents. It identifies worker group, jobs, and industries at potential risk from these exposures. This enhancement to the NOHSM project will provide resources for additional fiscal year 1988 field surveys, for documentation to be developed for the NOHSM data processing systems, for additional data entry and for the production of 100 additional facility site reports.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $12,000 | 21 |
| NEGOTIATED CONTRACTS | 70,600 | 25 |
| ADP EQUIPMENT | 10,000 | 31 |
| ALL OTHER EQUIPMENT | 1,550 | 31 |
| RENT, COMMUNICATION, UTILITIES | 1,400 | 23 |
| TRANSPORTATION OF THINGS | 4,450 | 22 |
| PERSONNEL COSTS AND BENEFITS | 40,600 | 11 & 12 |
| TOTAL | $140,600 | |

COAL MINER MEDICAL SURVEILLANCE: MORTALITY AND MORBIDITY TRENDS

RESEARCH UNDERTAKEN:

The Federal Coal Mine Health and Safety Act required that the average level of respirable dust in underground coal mines be controlled to 2 $mg/m^3$ or less, effective December 1972. This project evaluates whether this standard has caused a reduction in death and disfunction in miners due to exposure to coal dust.

Trends in the incidence of disease will be evaluated by analysis of chest X-rays taken in the coal workers' X-ray surveillance program. National and State trends in the occurrence of lung disease will be identified and reported. Trends in coal dust-induced deaths will be evaluated by analysis of National Center for Health Statistics multiple cause of death listings from 1968-1984. Trends will be analyzed by year and state.

In addition, meetings will be held with representatives of the Mine Safety and Health Administration (MSHA) and selected States to determine if there might be alternative, untapped data sources for surveillance of trends in coal workers' lung disease and, if so, to develop plans for analysis of this information.

DOLLARS ASSOCIATED WITH THE RESEARCH BY OBJECT CLASS:

| DESCRIPTION | BUDGET | OBJECT CLASS |
|---|---|---|
| DOMESTIC TRAVEL | $2,500 | 21 |
| NEGOTIATED CONTRACTS | 8,200 | 25 |
| ADP EQUIPMENT | 8,000 | 31 |
| SUPPLIES | 1,000 | 26 |
| PERSONNEL COSTS AND BENEFITS | 43,141 | 11 & 12 |
| TOTAL | $62,841 | |

Question. The report accompanying the FY 1988 bill also included language to provide $250,000 to establish an industrial medical center. What is the status of that project?

Answer. NIOSH has received applications under the project grants program. We expect to make an award by July 1.

Question. The National Institute of Occupational Safety and Health is the leader in its research and certification of respirators. Because of the recognition of that leadership, a cooperative training and research effort with the Air Force and the Appalachian Laboratory on occupational safety and health has been undertaken. What is the current status of the joint effort?

Answer. The National Institute for Occupational Safety and Health, Division of Safety Research, and the U.S. Air Force Institute of Technology have mutually agreed to the establishment of and participation in the Senior Health Policy Fellowship Program for the purpose of training Air Force officers in the areas of respiratory protective device research and certification, chemical protective clothing, and injury surveillance. During FY 1988, a USAF Senior Health Policy Fellow was assigned to NIOSH and we plan to continue this program in FY 1989 with a new assignee.

## QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

Question. How many weeks' supply of each of the childhood vaccines is currently in the stockpile?

Answer.

CDC Vaccine Stockpile
Status 5/2/88

| Vaccine | Purchased to Date # Doses | # of Weeks | Delivered to Date # Doses | # of Weeks |
|---|---|---|---|---|
| DTP | 5,569,995 | 13.8 | 2,608,995 | 6.5 |
| OPV | 6,611,000 | 20.5 | 6,611,000 | 20.5 |
| MMR | 1,680,000 | 20.8 | 1,129,500 | 14.0 |
| IPV* | | | | |
| DT | 400,000 | 20.8 | 400,000 | 20.8 |
| Td | 4,560,000 | 20.8 | 4,560,000 | 20.8 |

*New contract being negotiated

Notes:

1. The actual number of doses of DTP currently in storage is 2,494,995. This is due to a partial drawdown of the delivered stockpile by Connaught in January 1987, which has not been entirely replaced to date. This drawdown was approved by CDC to prevent shortages of DTP in the national delivery system due to production problems.

2. The actual number of doses of MMR currently in storage is 996,685. This is due to a partial drawdown of the delivered stockpile by Merck Sharp and Dohme in November 1986, which has not been totally replaced to date. This drawdown was approved by CDC to prevent shortages of MMR in the national delivery system due to production problems.

3. It is projected that an additional 634,500 doses of DTP vaccine and 19,180 doses of IPV will be added to the stockpile with appropriated funds in FY 1988.

Question. Will the vaccine surcharges authorized by P.L. 100-203 be collected on vaccines which are placed in the stockpile?

Answer. A preliminary opinion from the Internal Revenue Service indicates that the excise tax (surcharge) authorized by P.L. 100-203 will apply to vaccines which are placed in the stockpile.

Question. Will additional vaccine be added to the stockpile by the end of FY88?

Answer. During FY 1988, we plan to add an additional 634,500 doses of DTP vaccine to the stockpile. This assumes that the excise tax of $4.56 will be required. Without the excise tax, about 1,500,000 doses of DTP could be added in 1988.

Question. What would be the cost of completing the 6-month supply of each of the childhood vaccines by the end of FY 89?

Answer. The cost of vaccine needed to complete the stockpile depends on whether or not vaccine which is purchased for the stockpile remains subject to the excise tax. If payment of excise tax is required, it will cost an estimated $35,246,007 to complete the stockpile. If the excise tax is waived for vaccine which is purchased for the stockpile, the cost will be reduced to an estimated $10,288,137.

Question. What is the projected shortfall in funding for State operations in FY 88?

Answer. If we provide the new H-flu conjugate vaccine during the last half of fiscal year 1988, approximately $5 million will be available to support State operation in 1988. At the time the President's budget for 1988/1989 was developed, we were estimating that the 1988 appropriations would provide about $8.8 million for immunization State operations. This compares to $18.3 million which were available for State operations in 1987.

Question. I have heard from State departments of health regarding the reassignment of public health advisors from the immunization program to other CDC programs. How many States have already lost CDC staffers? How many CDC staffers will have left the immunization program by the end of FY 88? How many States will be affected by the reassignment of personnel?

Answer. In 1988, two States have lost an Immunization Program public health advisor, both because the advisors applied for and were selected for promotions. One was promoted within the Immunization Program while the other accepted a promotion in the AIDS program. With mutual agreement, one

State replaced the public health advisor with a highly qualified State employee. The other vacancy was announced, but has not been filled because of lack of highly qualified applicants and other issues related to a recent management study of the public health advisor field staff.

By the end of FY 88, we expect that up to six public health advisors will be promoted or reassigned to other positions or programs. We will probably have to defer filling five of the six vacancies until FY 89, or we may need to fill the vacancies with qualified State employees due to the unavailability of qualified public health advisors. These reassignments will probably affect a minimum of six States.

Question. I understand that a conjugate H-flu vaccine has been approved for use on 18-month-olds. I also understand that this new vaccine is more expensive that the vaccine which is currently used on 2-year-olds. What is the difference in cost of the two vaccines?

Answer. The cost of a single dose of the new H-flu conjugate vaccine in the private sector is $15.75 compared to $7.75 for a single dose of the old H-flu vaccine. The public sector cost of a single dose of the old H-flu vaccine is $2.17 per dose. We have not completed negotiations for a Federal contract for the new vaccine, but anticipate that it will cost between $10 and $12 without competition and between $7 and $9 with competition.

Question. Is FY 88 funding sufficient to purchase the new H-flu vaccine?

Answer. We have almost completed negotiations for the puchase of polio and DTP vaccines for the last half of fiscal year 1988 and the first half of fiscal year 1989. Based on these negotiations, we should be able to provide the new H-flu conjugate vaccine during the last half of fiscal year 1988. To accomodate this, funds for the support will be derived from about $8.8 million to about $5 million for fiscal year 1988.

Question. I also understand the conjugate H-flu vaccine might be licensed soon for use in infants and that if the vaccine is used in infants, a three dose series will be necessary. What is the cost of purchasing a three-dose series of the H-flu vaccine?

Answer. It is estimated that, with the competition, the new H-flu conjugate vaccine will cost $7 to $9 per dose or about $24 a series in 1989. Based on a three-dose schedule, 5.778 million doses will be needed to completely immunize the same number of children as were immunized at 18 months of age.

Question. Does the FY 89 budget request assume the three-dose series will be administered?

Answer. No. The FY 1989 budget assumes a one-dose series. At the time the FY 1989 budget was formulated, the conjugate H-flu vaccine had not been approved for children at 18 months of age. The vaccine has not yet been licensed for infants at six months of age.

Question. Does the request also reflect the additional cost of immunizing children between the age of three months and two years who have not received the H-flu immunization?

Answer. No. The 1989 request is for the same number of doses of H-flu vaccine that are included in the FY 1988 budget, 1.926 million doses.

Question. The FY 88 budget request assumes no funding for State operations. If the Congress agrees to this request, how many CDC Public Health Advisors will leave the immunization program? In what other ways will States feel the effects of the loss of State operations funds?

Answer. If State operations are eliminated, funds to support Public Health Advisors assigned to States will have to be obtained from other Federal, State, or local resources.

## AIDS EDUCATION FOR SCHOOL AND COLLEGE-AGED YOUTH

Question. For 1989, CDC is proposing to spend $26 million on educational programs directed at school and college-aged youth. What are you doing to measure the effectiveness of these programs?

Answer. A total of $36,450,000 has been requested in FY 1989 for information/education programs directed to school and college-aged youth. CDC has implemented several means to assess, and consequently improve, the effectiveness of these programs. CDC staff provided technical assistance to eligible applicants for cooperative agreements before proposals for funding were submitted to CDC for review and approval. This assistance helped applicants to develop specific, measurable program objectives and evaluation plans designed to assess progress in meeting established objectives. CDC requires each of the 15 national organizations, 15 State education agencies (SEA's), and 12 local education agencies funded in FY 1987 to provide information about the extent to which the agency attained its program objectives, and to use that information to improve the program. By the end of FY 1988, CDC anticipates funding the remaining 40 State and Territorial departments of education, approximately four additional local education departments, and approximately seven additional national organizations. CDC staff will also assist these agencies and organizations to assess and improve their programs.

CDC also provided technical assistance to funded State and local education departments to help them develop a common instrument to measure AIDS-related knowledge, beliefs, and behaviors among representative samples of junior and/or senior high school students in their respective jurisdictions. By the spring of 1988, almost all of the funded States and cities had collected information about the knowledge and beliefs of their students, and about half had generated information about the extent to which students engaged in behaviors that increased their risks for becoming infected with HIV. In FY 1988, CDC will provide assistance to enable the remaining State and Territorial departments of education to periodically assess AIDS-related knowledge, beliefs, and behaviors of junior and or senior high school students, and to assess the extent to which student knowledge and risk behaviors change over time. This information will be used by the States and cities to better target and improve their respective AIDS education programs.

Financial and technical assistance has also been provided to generate information about AIDS knowledge and beliefs from a nationally representative sample of 13,000 eighth and tenth-grade students. This information is part of the National Adolescent Student Health Survey implemented by the Association for the Advancement of Health Education, the American School Health Association, and the Society for Public Health Education. The information is currently being analyzed and will be used to determine what adolescents know and understand about AIDS.

CDC has also provided funds and technical assistance to the National Academy of Sciences to prepare a report (by the fall of 1988) describing the most important behavioral research that has been conducted and that should be conducted to control the AIDS epidemic. This report is being prepared to provide useful information about what we know from behavioral research about educational intervention designed to influence health behaviors, and to chart a course for future research to improve the effectiveness of our interventions.

Question. Could you update us on the spread of AIDS into the heterosexual population?

Answer. Thirty percent of all AIDS cases occur in heterosexual men and women, most of whom are intravenous drug (IV) abusers; 4 percent of all AIDS cases reported are attributed to heterosexual transmission. Much of the heterosexual transmission occurs from people infected through IV drug abuse to their sex partners. As of May 2, 1988, 2,463 heterosexual transmission cases have occurred in adults/adolescents; and heterosexual transmission is gradually increasing, especially in places where IV drug abuse is more prevalent. Geographically, this is more common in the eastern United States, mainly in the northeast and Florida. A disproportionate share of cases occurs in black and Hispanic minorities, but heterosexual transmission has been documented among all racial and ethnic groups. Heterosexual transmission occurs both from male to female and female to male and is the major route of transmission by which perinatal AIDS cases occur.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### AIDS EDUCATION FOR SCHOOL AGED CHILDREN

Question. Dr. Mason, the CDC section of the Department's Budget Justification for AIDS spending states: An analysis of surveillance data for adolescents showed that AIDS diagnoses have been increasing among adolescents as in other groups. The justification further states that: These data stress the need to begin risk reduction education early in adolescence to minimize the further spread of HIV infection.

The CDC has also published a report on Guidelines for Effective School Health Education to Prevent the Spread of AIDS.

Dr. Mason, would you please comment on the incidence of AIDS among teenagers in the country?

Answer. As of May 23, 1988, a total of 265 cases of AIDS have been reported to CDC among adolescents (aged 13-19) since 1981. This represents less than 1 percent of the total AIDS cases reported. An analysis of CDC AIDS surveillance data completed during 1987 showed that AIDS diagnoses have been increasing annually among adolescents as in other age groups. The majority of adolescents were exposed to HIV through sexual contact or IV drug abuse. High-risk behaviors may begin early in the teenage years; six AIDS cases due to exposure to HIV through sexual contact or IV drug abuse have been reported in patients as young as age 13-15. Of all adolescent AIDS patients, 15 percent have a history of IV drug abuse. Adolescent women with AIDS had delivered infants within the five years before the AIDS diagnosis, putting their infants at risk for potential HIV infection.

Seven percent of adult AIDS patients ($\geq$ 20 years old) were reported in 20 to 25 year olds, who may have acquired HIV infection as teenagers. These data stress the need to begin risk-reduction education early in adolescence to minimize the further spread of HIV infection.

### STD INCIDENCE AND SCHOOL AGED CHILDREN

Question. What about the incidence of other sexually transmitted diseases?

Answer. Teenagers have a disproportionate share of STD other than AIDS in this country. More importantly, when adjusted for level of sexual activity, the gap between the incidence of STD in teenagers and older persons widens. Various explanations have been proposed for this situation: increased levels of high-risk sexual activities among teenagers, increased biological susceptibility to sexually transmitted organisms, decreased health care seeking behavior, and increased denial or possible adverse consequences of sexuality.

Question. Do you believe we should be targeting these young people as a group that particularly needs information about AIDS and how to prevent contracting this fatal disease?

Answer. Young people are clearly an important group to target for AIDS education. A significant number of teenagers engage in sexual and drug abuse behaviors that increase their risk of becoming infected with HIV. In 1979, the average age at first intercourse for females in the United States was 16. In 1987, approximately 2.5 million cases of sexually transmitted disease occurred among teenagers. In 1986, about 1 percent of all high school seniors reported having used heroin and 13 percent reported having used cocaine within the previous year. We do not know the number who injected each of these drugs.

As they become sexually active, teenagers are at risk of becoming infected with HIV and transmitting the virus. However, studies have shown that they do not believe they are likely to become infected. Many teenagers in our society have a sense of invulnerability to injury or disease. Indeed, a random sample of 860 teenagers (ages 16-19) in Massachusetts revealed that, although 70 percent reported they were sexually active (having sexual intercourse or other sexual contact), only 15 percent of this group reported changing their sexual behavior because of concern about AIDS. Only 20 percent of those who changed their behavior selected effective methods such as abstinence or use of condoms. Most teenagers indicated that they want more information about AIDS.

We have evidence that planned and systematic comprehensive school health education, when implemented in grades kindergarten through twelve, can be effective in reducing high-risk behaviors for many types of health problems. Our young people also need effective education about AIDS appropriate to their ages that includes information on how they can protect themselves from infection.

Question. What efforts has the CDC made to reach these young children?

Answer. In FY 1987, with approximately $11 million, CDC launched an initiative to help schools across the Nation implement effective school health education to prevent the spread of AIDS. This initiative includes several strategies.

CDC has provided funds and technical assistance to 15 national organizations to help schools and other agencies serving youth implement AIDS education programs. Examples of national organizations funded are the National Parents Teachers Association, the National School Boards Association, and the American Association of School Administrators.

CDC also provided funding and technical assistance to 15 State and 12 city departments of education serving jurisdictions with the highest cumulative incidence of AIDS. These education departments are helping to implement effective AIDS education programs for young people within their jurisdictions. With almost $30 million in FY 1988, CDC plans to provide funds and technical assistance to the remaining 40 State and Territorial departments of education, approximately four additional city departments of education, and approximately seven additional national organizations. Additional funding was also provided to two of the funded States and one of the funded local education agencies to establish AIDS education training and demonstration centers. These centers will train approximately 400-500 personnel from across the Nation each year on how to implement effective AIDS education within their own jurisdiction.

CDC is helping to develop and disseminate a wide range of educational resources that are appropriate for school- and college-aged populations, including curricula, school programs, out-of-school programs, films and videotapes, filmstrips, audio tapes, teacher training programs, books, journal articles, and parent materials. CDC published Guidelines for Education and Foster Care of Children with HIV in 1985, and Guidelines for Effective School Health Education to Prevent the Spread of AIDS in 1988.

Finally, CDC is integrating evaluation research with program efforts to assess the impact of these various activities, and consequently to improve them. In FY 1989, funding for all of these activities is proposed to be increased to over $36 million.

## HIGH RISK YOUTH

Question. Dr. Mason, the CDC's Guidelines for Effective School Health Education to Prevent the Spread of AIDS, recommend that personnel from organizations other than schools should consider these guidelines in planning and carrying out effective education about AIDS for youth who do not attend school and who may be at high risk of becoming infected.

Dr. Mason, is there a need for targeting specific education programs to these youth?

Answer. School-aged youth who have dropped out of school may be at greater risk for becoming infected with HIV and for infecting their same-age peers who attend school than youth who attend school.

It is much more difficult to provide these individuals with effective AIDS education programs and to influence their behaviors as they may well be isolated from the very social institutions (schools and families) that can help them adopt behaviors to protect them from becoming infected, or to cope if they are infected with HIV. There is clearly a need to target AIDS education programs to these youth.

Question. How much, if any, money is included in the CDC's FY89 budget to specifically target these young people?

Answer. By the fall of FY 1988, CDC anticipates having funded a total of approximately 22 national organizations with the capacity, experience, and constituencies to help schools and other institutions serving youth provide effective education about AIDS. Fifteen such national organizations were initially funded in FY 1987. Four of these organizations are specifically targeting their efforts toward out-of-school and minority youth. The National Network of Runaway and Youth Services is working with the 290 Federally-funded runaway and homeless youth programs, three national runaway hotlines, and other youth-serving agencies that belong to the Network. The National Coalition of Advocates for Students is providing AIDS education for migrant youth, immigrant youth, and disadvantaged youth living in the "blackbelt" counties of the Southeast. The Coalition of Hispanic Health and Human Services Organizations and the National Organization of Black County Officials are addressing the specific needs of Hispanic and black youth respectively as well as the needs of out-of-school youth.

In FY 1988, CDC anticipates funding a national organization representing health care providers serving the needs and interests of youth who are in correctional institutions.

In FY 1989, CDC plans to continue support to these national organizations serving the needs of out-of-school and minority youth in the amount of approximately $750,000.

Schools also play a role in AIDS education for out-of-school youth. Most of the 15 State and 12 city departments of education funded in FY 1987 to provide AIDS education for school students in their respective jurisdictions are also helping to provide AIDS education for school-aged populations that do not attend school. For example, State and city departments of education work with juvenile justice and correction agencies, children and youth social service agencies, community substance abuse programs, and migrant health programs to help train youth workers, develop or disseminate AIDS education materials, and plan AIDS education programs for youth who do not attend school.

In addition, schools play a direct role in influencing the number of young people who stay in school. Many young people drop out of school as a result of preventable health problems, e.g., drug abuse and unintended pregnancy. Effective school health programs could substantially reduce the number of those who drop out of schools by providing education in these areas. This is one of the reasons CDC advocates comprehensive school health programs for grades kindergarten through 12.

By the fall of 1988, CDC plans to having funded the remaining 40 State departments of education and approximately 4 additional city departments of education to help schools and other organizations provide effective AIDS education for youth.

## AIDS CLEARINGHOUSE

Question. Dr. Mason, what is the status of the AIDS clearinghouse and what are your plans for the clearinghouse in FY 1989?

Answer. The National AIDS Information Clearinghouse was created through a competitively awarded contract in September 1987. Immediately after the award, in November, the publication distribution services were initiated. From the award of the contract through April 15, 1988, the Clearinghouse has distributed over 22 million general information brochures to the public.

The Clearinghouse has developed two databases of organizations and educational materials which are available throughout the United States. These databases will continue to be developed throughout the contract, and will serve as the central resource file for all of the programs involved in AIDS information and education activities. Reference specialists began using these databases to respond to inquiries from AIDS program managers and other public health professionals in April, and will offer these services throughout the life of the contract. These reference support services are available to everyone, but are designed for assistance in the development and management of programs.

The Clearinghouse has implemented or is developing other program features, such as link with the National AIDS Hotline, plans for a bulletin board, and technical support to State AIDS Programs in local program development.

Plans for 1989 are to expand the scope of the databases and to provide any additional reference specialists required to respond to the demand for consultation. Additional databases will be developed, or acquired as necessary, to respond to any information gaps in the resources available for providing assistance to AIDS program staff or the public. Coordination with other PHS Information Services will be enhanced.

A specific priority area for 1989 will be providing outreach efforts to improve the ability of users to access and benefit from the services. This will include: training and other technical assistance; the development of specialized resource materials and reference guides; and collaboration with key national and State AIDS program personnel.

## AIDS - BLOCK GRANTS

Question. Dr. Mason, are there plans at the CDC to block grant AIDS education and prevention money to the States?

Answer. CDC has no plans to block grant education and prevention funds to the States. However, CDC has and will continue to seek methods for streamlining the administrative procedures by which States apply for and are awarded AIDS education and prevention funds through cooperative agreements. For example, in FY 1988, applicants were only required to submit a single, consolidated application to compete for funds to support the following activities: surveillance; seroprevalence surveys; health education/risk reduction; counseling, testing, and partner notification; public information; and reaching minorities at risk. Funds are awarded based upon documented need, as well as a demonstrated ability to perform.

Question. How would this differ from how the funds are provided now?

Answer. Prior to FY 1988, applicants submitted separate applications to CDC to compete for cooperative agreement funds for each of these projects.

Question. Will this proposal require legislative approval?

Answer. The current system of combining State AIDS education and prevention projects into a consolidated cooperative agreement is being done administratively, and no legislation is required. There are no legislative proposals in this area in the President's budget request for FY 1989.

Question. How would such a grant program affect the National Campaign effort?

Answer. The current consolidated award system should have little if any effect on the National Public Information Campaign since those funds are not awarded to the States, and there are only limited restrictions on the States' use of the consolidated cooperative agreement funds for AIDS prevention/education efforts to complement the National Campaign.

## AIDS SERVICES PROVIDED BY STATES

Question. What assurances will you have that the States are providing the services needed and targeting communities where the incidence of AIDS may be disproportionately higher than in the general community?

Answer. CDC closely monitors the cooperative agreements to ensure that the States are providing needed services particularly in areas with a disproportionately high incidence of HIV infection. For example, in order to receive authorization to expend funds to reach minorities at risk, States are required to provide detailed information regarding potential community-based minority organization subcontractors.

## AIDS HOTLINE

Question. Dr. Mason, I understand the number of calls being received by the AIDS hotline has far exceeded expectations. Is that correct?

Answer. The number of calls which have been received at the National AIDS Hotline have increased dramatically as a result of our efforts to inform and educate the American public. From the initial operation of the Hotline through October of 1987, the demand for Hotline services was no more than 900 calls per day. The National AIDS Information Campaign implemented by CDC last fall more than doubled the public's use of this information resource, and has resulted in a continued demand for services at the rate of over 2,000 operator assisted calls per day. The Hotline provides a taped message of approximately 2 and 1/2 minutes that allows the caller to obtain some basic information on AIDS. For the week ending April 30, 24,633 callers received this taped message.

Callers who listen to the taped message are provided a second number which allows them to speak with an operator for additional information. For the week ending April 30, 15,640 calls were answered by operators.

Question. How many calls per week is the hotline receiving? Per month?

Answer. From January 1, 1988 through April 30, a total of 503,935 calls were made to the Hotline for an average of approximately 31,500 per week and 126,000 per month.

Question. How much money will be spent on the Hotline in 1989?

Answer. CDC has requested $2.7 million for the Hotline in FY 1989, which will supplement funds awarded at the end of FY 1987 for the operation of the Hotline through FY 1990.

Question. Will that be enough to respond to the demand?

Answer. The amount requested for the Hotline in FY 1989 should be adequate. If the demand continues to greatly exceed even our latest revised estimates, we will do whatever is necessary to maintain this valuable service and respond to the need.

Question. How does the 1989 request compare with the 1988 appropriation?

Answer. The amount requested in FY 1989 exceeds the $2.284 million appropriated for FY 1988 by $416,000.

## ORIGINAL BUDGET REQUEST

Question. Dr. Mason, what was the CDC's original budget request to the Public Health Service budget office for FY89? (including AIDS?).

Answer. The original request including AIDS was $1,118,918,000

Question. Without AIDS?

Answer. The CDC request without AIDS was $718,199,000.

Question. How do these numbers compare with the budget request before us this morning?

Answer. The request includes $400,719,000 for AIDS, the same as our request, and $523,146,000 for non-AIDS.

## FTE REQUEST

Question. Dr. Mason, how many total FTE positions did you request (including AIDS) with your original budget request?

Answer. CDC requested 4,776 FTEs for FY 1989.

Question. How many are you requesting in the President's budget?

Answer. The President's request includes 4,405 FTE for CDC. However, this excludes an additional 585 FTEs assigned to States in-lieu-of cash awards that are now ceiling exempt, beginning in January 1988. If these FTEs were included, then the 1989 FTE level would be 4,990 compared to the 4,776 FTEs originally requested to PHS.

Question. How many of these are for AIDS?

Answer. There are 432 for AIDS.

Question. How many for non-AIDS?

Answer. For non-AIDS, there are 3,973 FTEs, excluding 585 ceiling exempt State assignees.

Question. How do the non-AIDS positions compare with the numbers allocated in FY88?

Answer. There is a decrease of 16, due to planned management improvement savings.

## CHILDHOOD IMMUNIZATION REQUEST FOR 1989

Question. While the immunization budget request does provide a small increase for FY89 it is still not enough:

- All funds to assist States to administer the program are eliminated (-$18 million)
- All funds for vaccine stockpile are eliminated (-$4 million)

Question. Dr. Mason, how much did the CDC originally request for the Childhood Immunization Program for FY89?

Answer. CDC request to PHS included $137,261,000 for the immunization program.

Question. Did the CDC propose eliminating all funds to assist States to administer the immunization program?

Answer. CDC did not propose to eliminate funds for State operations.

Question. Did the CDC propose eliminating all funds for the vaccine stockpile?

Answer. No, CDC requested funds to continue building the stockpile.

## IMMUNIZATION PROGRAMS - STATE FUNDING

Question. Do you have any indication from the States that they will be able to cover the last administrative costs at the same time we are asking them to pay a new surtax on all vaccines?

Answer. We are hopeful that there will be minimal effect on State vaccination programs from decreases in the portion of the Federal grant available for State immunization program operations. We realize that State operations are an important component of immunization programs. However, the immunization program is one where the Federal and State governments share the financial responsibility. Our budget request provides sufficient funds to purchase the same number of doses of vaccine which were provided in 1987 and in 1988, and the provision of vaccine is our highest priority. For that portion of public sector vaccines paid for with Federal funds, the cost of the new excise taxes for 1989 have been fully covered within the proposed budget request.

Question. What is to stop States from cutting back on their vaccination programs if they don't have the money to administer them?

Answer. Immunization Grants are awarded to States and localities to assist them in conducting their immunization programs. While there is nothing that would prevent States from cutting back on their immunization programs, we assume the States share this commitment to this cost effective program for the children of their States.

Question. Isn't the Federal contribution to State administrative costs a mechanism for maintaining a kind of quality control over this program?

Answer. The Federal contribution to State administrative costs can be viewed as a quality control mechanism; however, the grant guidelines which control the condition of grant awards and immunization program reviews by CDC personnel are the specific mechanisms which CDC uses to more effectively influence the quality of State and local immunization programs.

## H-FLU VACCINE

Question. Dr. Mason, in 1987, acting on information provided to me by the CDC, I urged the subcommittee to appropriate an additional $5 million in the childhood immunization program to cover the cost of a new H-Flu vaccine. Now, I understand there is an even better but more expensive H-Flu vaccine. Is there enough money in the FY89 budget request to pay for the new vaccine for the same number of vaccine doses as the old vaccine?

Answer. A new H-Flu conjugate vaccine was approved for use in the United States late in 1987. This vaccine is a more effective vaccine in younger children and is currently recommended for use in children 18 months of age and older. The older H-Flu vaccine was not recommended for use in children less than 24 months of age. The new vaccine currently sells for $15.75 for a single dose in the private sector compared to $7.55 for a single dose of the old vaccine in the private sector. We have not yet completed negotiations for a Federal contract for the new vaccine, but anticipate that it will cost between $10 and $12 without competition and between $7 and $9 with competition.

Despite this higher cost for the new H-Flu vaccine, we should still be able to provide in FY 1989 the same number of doses of the new H-Flu vaccine as we had planned to provide of the old vaccine within the resources requested. This is possible because, based on our nearly completed negotiations, we now expect that the prices for polio and DTP vaccines for the last half of FY 1988 and the first half of FY 1989 should be less than we estimated at the time the FY 1989 budget request was developed. The savings from this earlier estimate for polio and DTP vaccines should be able to be applied to the purchase of the new H-Flu vaccine.

Question. Am I correct that the new vaccine will be approved for children who are 6 months old?

Answer. Vaccine manufacturers and the Food and Drug Administration are currently reviewing data on the effectiveness of this conjugate H-Flu vaccine when administered to infants. It is hoped, and we believe likely, that this vaccine will be approved in the near future for children who are 6 months of age, though the timetable for potential approval is not certain.

Question. And the current vaccine is administered at 24 months?

Answer. The current ACIP recommendations are that the new conjugate vaccine can be administered at 18 months of age; the old one was regarded as effective at 24 months of age.

Question: What will happen to those children who fall in the middle? Those who may be 7 or 8 or 23 months of age?

Answer. Of the estimated half of all U.S. children who receive immunizations through the public sector, some (i.e., those at least 18-24 months old) will be covered by the new conjugate H-Flu vaccine within the same year as planned for the old vaccine within the same year as planned for the old vaccine. If the vaccine is proven to be effective for children at 6 months, we would expect that the balance of children (between 6-18 months) who had not yet been immunized will be caught up by the States over time.

Question: Do you have enough money to pay for all of the doses that will be required to cover all of these children?

Answer. Although the Federal consolidated contract prices for the new vaccine have not yet been finally determined, we believe the 1989 request would provide sufficient funds for purchasing 1.928 million doses, the same number of doses as purchased in 1988.

## RECRUITMENT PROBLEMS

Question. Dr. Mason, the proposal floated by OMB some months back concerning the privatization of NIH, raised a number of concerns about recruiting and retaining top scientists and public health experts at the NIH. While I can assure you, I would oppose such a proposal to privatize the NIH, or any other public health agency, I am concerned about attracting and keeping the best and the brightest at all of our public health agencies.

Are you having any recruitment problems at the CDC?

Answer. We are experiencing increasing difficulty in recruiting and retaining senior scientific staff at the CDC. The number of candidates indicating the reason for not accepting employment at CDC is that salaries and benefits are not competitive with the private sector and the number of CDC scientists who are leaving for the same reason has accelerated at an alarming rate. Top scientific vacancies are advertised widely and search committees aggressively seek out candidates with disappointing results. Several of our key scientific positions have been vacant from several months to two years because of our inability to attract highly qualified candidates.

We are also experiencing increasing problems with retaining our top scientific staff. Non-federal employers are attracting our expert scientists with offers of large increases in salary and benefits. On the other hand, Federal service offers scientists some benefits which have great appeal. For example, CDC scientists are not required to have teaching loads; are not required to attract grant funds annually; are freer to pursue long-range projects which have no immediate payoff in terms of publication of results; and may pursue knowledge for knowledge's sake, rather than for profit. These benefits do appeal to many scientists. However, we continue to have concerns about our ability to retain senior scientists.

Question. If so, would you please provide the committee with details on these problems, and what factors you believe are contributing to such problems?

Answer. Several of our key scientific positions have been vacant for several months to 2-3 years because of our inability to attract the best scientific talent. I can best illustrate the nature of this problem by citing some examples:

- Our Chief, Retrovirus Branch, Center for Infectious Diseases, has been vacant for approximately 15 months with no hopes of attracting a candidate in the near future in spite of a concentrated search. Top candidates with the required expertise declined consideration primarily due to salary inequity. One individual would have had to take a $20,000 reduction in base pay plus less generous benefits that were completely paid for by his employer.

- The Director, Division of Viral Diseases, Center for Infectious Diseases, position has been vacant for six months with one of our most extensive searches for candidates being conducted. Yet, even though this a Senior Executive Service (SES) position, a number of prospective candidates have declined consideration due to salary considerations. Several who were identified elected not to apply because of salary discrepancies and some of the highly qualified applicants withdrew from consideration for the same reason. The pay differential range for the top four civilian candidates was $37,000 to $54,000 above the maximum pay allowable for this SES position.

- Our Director, Hepatitis Branch, Center for Infectious Diseases, will direct a medically oriented research program. The search committee approached several highly qualified physicians who would have had to accept cuts of more than one-half their current salaries. We advertised widely in professional journals with no success.

- The Director, Pathology Research, National Institute for Occupational Safety and Health, has been vacant for two years. This has resulted in a reduction of our research and an important legislatively-mandated autopsy service for miners killed on the job is being done on an ad hoc basis using outside pathologists. A highly qualified applicant who would have greatly enhanced our research declined because we could not offer a salary competitive with his medical school appointment.

- The Director of our Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, a world-renowned expert in byssinosis, was successfully recruited by the University of Iowa Medical Center as Professor of Occupational Health because we could not offer reasonably competitive salary and benefits.
- The Division Director of our Surveillance, Hazardous Evaluations and Field Studies, National Institute for Occupational Safety and Health, was recruited by the Mount Sinai Medical School for the position of Chairman, Occupational Safety and Health at a salary more than double his CDC salary. In addition, his benefits include annual tuition payments for three of his college age children.
- The Chief of our Viral Exanthems and Herpesvirus Branch, Center for Infectious Diseases, recently left CDC to accept a position with Lilly Corporate Center for a salary that doubled his civil service pay, offered fully-paid benefits, his own laboratory with new equipment, and the authority to hire a staff of 45 researchers.

Our recruitment and retention problems are caused primarily by salary and benefits disparities. While we cannot expect federal employment to be fully competitive with academia and industry, we should be able to offer a reasonably comparable pay and benefit package that could attract and retain top scientific talent.

Question. What recommendations do you have to alleviate the situation?

Answer. A system such as the proposed Senior Biomedical Research Service would greatly reduce this problem by providing flexible and reasonably comparable pay and benefits for our top scientific personnel. In addition, a significant increase in flag rank and SES positions would be a major step in the right direction, even though salaries in these systems are not as competitive in many cases. CDC has requested, and the Public Health Service and the Department are working cooperatively with us in an effort to make more of these limited executive level scientific positions available.

A Senior Biomedical Research Service would have an extremely important impact on the morale of our top scientific staff and our ability to recruit and retain the talented people we need to carry out our prevention mission.

## DEVELOPMENTAL DISABILITIES

Question. The National Council on the Handicapped has requested that this subcommittee increase the funding of programs geared toward the prevention of disabilities.

Last year, Congress appropriated $3.8 million to the Centers for Disease Control for a grant program to assist communities develop programs aimed at the prevention of disabilities. How many States are now receiving funds for this program?

Answer. To date, no funds have yet been awarded. However, prior to the end of FY 1988 CDC plans to award cooperative agreements to approximately ten States.

Question. Could you describe some of the program plans which those States are developing?

Answer. The Program Announcement for this program is expected to be published in the Federal Register in June 1988 and applications will be submitted and reviewed by CDC in August 1988. The Program Announcement outlines the program plans that States should develop for the prevention of disabilities. These plans include:

- Creation of a State advisory body to review and coordinate efforts to prevent all major types of disabilities.
- Establishment of a State office of disability prevention to develop plans and objectives for the State and communities and provide technical assistance to communities.
- Implementation of community projects in selected targeted disabilities: developmental disabilities, injury disabilities from head and/or spinal cord trauma, and secondary disabilities in persons with physical disabilities.

In addition, CDC will fund projects to develop a disabilities prevention information base. Examples of projects to be funded are:

- Determine incidence and prevalence rates of selected disabilities;
- Evaluate the feasibility of establishing regional and national surveillance systems; and
- Document the effectiveness and costs of preventive interventions.

Question. How much have you requested for this program in FY 1989?

Answer. The FY 1989 budget request includes $3.83 million for the disabilities prevention program.

## LYME DISEASE

Question. Dr. Mason, as you know Lyme disease is a disorder that has particular concern to me as a Senator from Connecticut. First identified in Connecticut, Lyme disease has grown to be the most common tick-borne disease reported to your agency. I understand the CDC has established objectives for the implementation of a comprehensive initiative aimed at addressing the problem of Lyme disease. Would you briefly describe the components of this initiative, what activities in FY89 will the CDC be involved in and how does the initiative interface with other public health service activities?

Answer. The objectives of the initiative are to institute a comprehensive research and development program in CDC aimed at the control of Lyme disease (LD) in the United States.

Specific objectives include:

- Improved surveillance for infection and disease in humans and domestic animals of special importance;
- Definition of the present distribution of _B_. _burgdorferi_ (organism causing LD) and its tick vectors and future movements in the U.S.;
- Elucidation of the mammalian and avian vertebrate hosts and their role in transmission and dissemination of _B_. _burgdorferi_;
- Colonization of potential vector species and definition through experimental studies of vector competence and mechanisms underlying replication, tissue dissemination, and transmission of _B_. _burgdorferi_;
- Development of improved diagnostic tests;
- Definition of geographic variation of the etiologic agent; and
- Development and evaluation of tick and rodent control strategies.

Objectives contained in the initiative will be met by establishing close working relationships with State health departments, state and local vector control agencies, the Harvard School of Public Health, Ball State University, and NIH/NIAID in Hamilton, MT.

In FY 1989, CDC will: (1) continue to consult with the Committee of State and Territorial Epidemiologists to design a more efficient and specific surveillance system; (2) complete development of a two-site enzyme immunoassay for the detection of the disease-causing organism in tissue samples and ticks; (3) continue to evaluate commercial reagents for the detection of Lyme disease; and (4) continue antibody testing for reference diagnosis and for special studies.

## CHRONIC DISEASES

Question. Dr. Mason, I understand you have made prevention of chronic diseases a top priority at the CDC. What is the CDC doing to implement such prevention efforts?

Answer. We have begun to work with voluntary health organizations, professional associations, and others in the private sector to mobilize a coalition committed to a common course for the prevention and control of chronic diseases. To facilitate that purpose and to provide a forum for the exchange of information and experiences, CDC and the Association of State and Territorial Health Officials have co-sponsored two national conferences on chronic disease prevention and control. The third conference will be held in Denver, Colorado, this fall.

As you know, we are addressing smoking and other behavioral risk factors related to cardiovascular diseases and cancer, and are working with the states in the control of diabetes and its complications and in the prevention of dental disease. During the past three years, we have undertaken cooperative agreements with several states to assist them in organizing and carrying out effective chronic disease intervention programs at the community level (Alabama, Maine, and Ohio, with direct involvement of eight target communities).

We have collaborated with a number of states in demonstration projects related to the prevention and control of cardiovascular disease (South Carolina), cervical cancer (Kentucky, Illinois, and Georgia), and cancer in general (Connecticut). We are assisting the State of Rhode Island to evaluate a comprehensive breast cancer screening program, and plan to extend breast cancer screening efforts to additional areas this year.

Question. How much have you requested for these efforts in FY 1989?

Answer. For the specific chronic disease prevention initiatives described above, the 1989 President's budget includes $5.8 million. The request also includes another $37.6 million for other CDC activities designed to control and prevent chronic and environmental diseases.

Question. How does that compare to FY 1988?

Answer. That provides level funding for these activities.

Question. In your professional judgment, should we be spending more in this area?

Answer. A great deal has been learned about how to prevent and control the chronic diseases that currently are the leading causes of disability and premature death in the United States. Unfortunately, these preventive interventions are not reaching large segments of the population groups that are at high risk of these conditions. CDC has an opportunity and, we believe, a responsibility to provide leadership in the dissemination and efficient application of prevention technology to alleviate the public health burden of these diseases. To meet that responsibility, we believe, requires that CDC assist the states in developing their capacity to carry out effective programs based on modern concepts and technology. It requires that emerging chronic disease prevention methodologies be tested and demonstrated in the community, and that public health workers at the state and local levels be trained in the application of new techniques.

We are convinced that the coordinated efforts of public health agencies at the Federal, State, and local levels; voluntary agencies, such as the American Cancer Society, the American Heart Association, the American Diabetes Association, and others; private medical and allied health practitioners; and the academic community can begin now to have an impact on these problems. For example, technology that is already available could be applied intensively to reduce greatly, and eventually eliminate the thousands of unnecessary deaths each year that result from cervical and breast cancer. Although additional resources would be required for such an intensive national effort, the overall savings in direct and indirect costs of those diseases in this country would be substantially greater.

CDC's 1989 budget continues to support an extensive and wide-range of chronic disease prevention and control programs in specific States and communities. However, offsets have not been identified within the budget request that would be required to accommodate further program increases and remain within the budget request that would be required to accommodate further program increases and remain within the ceilings of the Bipartisan Budget Agreement for 1989.

## STD BUDGET REQUEST

Question. Dr. Mason, CDC data indicates that there have been dramatic increases in the incidence of sexually transmitted diseases over the past two years. In fact, I understand syphilis has increased by more than 100 percent in some cities. Yet, the Administration's budget request for the Sexually Transmitted Disease Program is essentially level funded. How do you explain freezing this budget when the need for services has so greatly increased?

Answer. You are correct that the incidence of many STD, especially those causing genital ulcers, is increasing in the United States. By shifting the resources within the $54.8 million requested for the STD grant program, we expect to be able to control those infections which have increased, without losing the momentum we have gained on those that have decreased, such as uncomplicated gonorrhea. In addition, we expect that the significant Federal investment in AIDS prevention/education activities, for which $374 million are requested for 1989, we pay eventual dividends in terms of changing behaviors to reduce the levels of other STD as well.

Question. What was your original budget request for this program?

Answer. The original request to the Public Health Services was $117.44 million for STD activities.

STD - RISE IN INCIDENCE

Question. To what do you attribute the increase in STD's over the last few years?

Answer. A variety of explanations have been offered to account for the rise in STD over the last few years: increases in the population at risk, especially those difficult-to-reach populations exchanging sex for drugs/money; increases in the number of strains resistant to our traditional antibiotics; increase in several STD (e.g., genital ulcers) that lead to the acquisition and/or transmission of other STD (e.g., HIV); and general increases in the incidence of STD in the high-risk population which leads to exponential growth of these infections within a given community.

STD CONTROL FTEs

Question. Please provide for the Committee an accounting of the number of FTEs available to the STD Control program over the past 5 years. Please also detail the number of FTEs which have been transferred during the past five years from STD control to AIDS activities.

Answer. The budget for our STD programs averaged 555 FTEs for the period of 1983-1986. In 1987 that number was reduced by 44, due to transfers from STD control to AIDS. Of these, 33 were field assignees and 11 were assigned to headquarters in Atlanta. In the FY 1988 appropriation, the field staff provided in-lieu-of-cash positions were removed from the FTE ceiling. We can now plan to provide field staff necessary to maximize the STD funds available.

Question. Among those personnel still assigned to STDs, what percent actually spent all of their time on STDs? What percentage of their time is spent on AIDS activities?

Answer. Because their expertise in STD is easily transferable to and integrated with AIDS activities, it is logical that there will be cross-over from STD to AIDS and from AIDS to STD. A survey of STD staff late in 1987 indicated that 89 percent of STD funded employees were devoting some of their time to AIDS activities. Funds to support the AIDS activities of STD employees came from AIDS resources and not STD. The amount of time varied widely, from 5 percent to 95 percent. However, the same survey indicated that 79 percent of AIDS funded employees were devoting some of their time to STD activities. The percentages were considerably lower, ranging from 5 percent to 50 percent.

## STD AND AIDS

Question. Dr. Mason, I understand that sexually transmitted diseases may be considered co-factors in the development of AIDS. Could you please explain the association between infection with an STD and an infection with HIV?

Answer. You are correct that in both Africa and the United States, genital ulcer diseases have been associated with increased risk of HIV seropositivity. The most biologically plausible explanation for this association is that loss of epithelial integrity can provide the portal of entry (or exit) apparently needed by HIV to reach the receptor-bearing $T_4$ cells.

Question. If we could prevent infection and spread of STDs, could we also prevent the spread of HIV?

Answer. For those STDs most associated with transmission/acquisition of HIV, effective control of these organisms would reduce the potentiating effect which their presence would have on HIV infection.

## GONORRHEA RESISTANT TO ANTIBIOTICS

Question. What has been happening to rates of gonorrhea which is resistant to antibiotics over the past eight years?

Answer. While the total number of cases of gonorrhea has been decreasing in recent years (largely due to Federal resources directed to a national gonorrhea control program), the percentage of gonorrhea resistant to such antibiotics as penicillin and tetracycline has been markedly increasing. Moreover, the complexity of the mechanisms by which the gonococcus is becoming resistant has also increased, to include both plasmid-mediated and chromosomally-mediated resistance.

## CHANCROID

Question. Chancroid is a disease we hear very little about. What has happened to rates of this disease in the past two years?

Answer. Although chancroid occurs at relatively low levels in the United States, incidence has significantly increased over the past several years. For example, in 1985 we had less than 1,000 reported cases, whereas in 1987, over 4,000 have been reported.

Question. To what do you attribute these increases? To what degree has a lack of sufficient funding and personnel had an impact on our ability to control these diseases?

Answer. A variety of explanations have been offered to account for the rise in STD over the last few years: increases in the population at risk, especially those difficult-to-reach populations exchanging sex for drugs/money; increases in the number of strains resistant to our traditional antibiotics; increase in several STD (e.g., genital ulcers) that lead to the acquisition and/or transmission of other STD (e.g., HIV); and general increases in the incidence of STD in the high-risk population which leads to exponential growth of these infections within a given community. Clearly, our past experience with the control of such STD as syphilis and gonorrhea has shown that applying resources (both human and fiscal) can have an impact on reducing these infections.

Initially, before Federal AIDS assistance to the States was significantly expanded, existing STD resources were stretched in order to respond to the new threat of sexually-transmitted AIDS infections. However, with now over $374 million expected to be spent on AIDS prevention/education efforts in 1989, which includes $102 million specifically for AIDS testing, counseling, and partner notification, States should be able to avoid such short-term trade-offs and concentrate again on control and prevention of other STDs.

## VIRAL STD

Question. Although several of the STDs, such as syphilis, gonorrhea and chancroid are bacteria and can be treated, there are several STDs caused by viruses, such as herpes and HPV. How much do the State grants devote to the control of these diseases?

Answer. In FY 1987, STD project areas devoted 2.5 percent of funds to such viral STD as herpes and HPV. At the present time, we do not have technology to allow effective secondary prevention programs to be directed to these particular viral STD. As such, most of our prevention activity has been emphasizing primary prevention, much like the same messages which reduce the spread of HIV.

## HPV INFECTION

Question: How many Americans suffer from HPV? What are the dangers of this infection? What can happen to infants who acquire the infection?

Answer. An estimated 10 million Americans suffer from HPV, including those who seek treatment for external genital warts as well as those who have cervical HPV detected on PAP smear. The most serious danger from HPV is the risk of cervical carcinoma. Increasing evidence shows that specific sub-types of HPV, especially sub-types HPV 16 and HPV 18, can lead to progression of cervical neoplasia from a genigh to a more malignant state. Infants who acquire the HPV infection during the birth process are at risk of laryngeal papilloma, which in certain circumstances can be life threatening if they block the air passage through the larynx.

## CONTROL OF VIRAL STD

Question. STD prevention and control has been largely devoted to the control of diseases for which diagnosis and treatment are available. How can we begin to adequately address the control of viral STDs which are often difficult and expensive to diagnose and for which effective treatment is not available?

Answer. Viral STD can be controlled through several mechanisms. First, like HIV, prevention of infection is paramount. The same messages which serve to prevent the spread of HIV will have a concomitant effect on the other viral STD. Second, research is proceeding to make diagnostic procedures less expensive and more widely available for such conditions as genital herpes and HPV. Third, as a result of intensive research looking at cures for HIV, other antiviral therapy spin-offs may serve to treat the other viral STDs. As this technology develops, we can adapt STD control programs to include diagnostic and treatment entities for the viral STD in their standard intervention practices.

## CHLAMYDIA

Question. How many Americans acquire chlamydia each year? Is this a treatable disease? I understand many women can have the disease yet have no symptoms and be unaware of their infection. Is that true?

Answer. An estimated 4 million Americans are infected with chlamydia each year. Chlamydia is easily treated through a common antibiotic, tetracycline. Unfortunately, chlamydia is asymptomatic in many women, who often do not realize they are infected with this organism until they realize they are infertile.

Question. How much are we spending this year to control chlamydia? How much will we spend in FY 1989? Do the States feel that they have adequate resources to deal with this problem?

Answer. In FY 1988, we will spend $8,800,000 on grant programs for chlamydia prevention and control. We expect to spend the same level in FY 1989. We have no systematic quantitative data as to the availability of all other sources of funding for State and local health departments to use for this purpose.

Question. You have testified before this Committee in past years of the importance of instituting a national control program for chlamydia. Do you feel that it is possible with this budget request?

Answer. In 1985, CDC issued guidelines to the States for their use in establishing chlamydia control programs. Many States have selectively instituted programs directed to high-risk individuals, allowing for the most cost-beneficial expenditure of chlamydia control dollars. There are always more opportunities than resources allow to cut other chains of transmission in communities. However, offsets have not been identified within the budget request that would be required to accommodate further program increases and remain within the ceilings of the Bipartisan Budget Agreement for 1989.

## STD PUBLIC EDUCATION

Question. How much did the STD division allocate to programs of public education in FY 1988?

Answer. In FY 1988, the Division of Sexually Transmitted Diseases allocated approximately $6,400,000 for public education at the State and local level.

Question. How much will the Division spend in FY89 on public education for sexually transmitted diseases? What were these programs?

Answer. In FY 1989, we will spend approximately $6,400,000 for public education activities. The educational message varies with the target group. The major target groups and their respective messages are:

- o Patients
  - Take all medication as directed
  - Return for followup tests
  - Assure that all sexual partners are examined
  - Take reasonable steps to reduce the future risk of infection
  - Respond promptly to future disease suspicion by curtailing sex, presenting for medical care, and bringing sex partners or information with which to locate them at the time of examination.

- o Health care providers
  - Make accurate diagnoses using appropriate diagnostic tests
  - Follow guidelines for specimen collection and handling
  - Follow recommended STD treatment guidelines
  - Report eligible cases promptly and completely
  - Counsel patients to refer all sex partners to medical care, take all medication as prescribed, and modify their behavior to reduce the risk of future infection.

- o Distinct Risk Groups/General Population
  - Eliminate the risk of STD either through sexual abstinence or a mutually faithful relationship with an uninfected partner
  - Reduce risk of infection through the proper use of condoms; risk increases with the number of sex partners and the risk status of sexual partners.
  - Recognize and respond to disease suspicion.

Question. Were any of them national in scope?

Answer. CDC's approach has generally been to work with States to provide targeted information for the media, public and private school systems, and private organizations. Even within States, the populations at risk are different and require different messages. In California, for example, Hispanic residents of Los Angeles receive a very different educational message than teenage homosexuals in San Francisco. However, several of the public education programs funded were national in scope: the STD and AIDS National hotlines, the STD prevention/training centers located in regions throughout the country, as well as continued promotion of "STD-A Guide for Todays Young Adults," for use in junior and senior high schools nationwide.

## MARRIAGE AND DIVORCE DATA COLLECTION

Question. I have been told that the National Center for Health Statistics is considering eliminating or reducing its program of collecting data on marriage and divorce in the United States. Is that correct? Why is such a cutback being considered?

Answer. The FY 1988 and 1989 budget request contains sufficient funds to maintain a basic marriage and divorce program. There are currently no plans to eliminate the national marriage and divorce vital statistics system.

Question. Is this information available anywhere other than at the National Center?

Answer. Annual counts of marriages and divorces occurring in the United States are available only from NCHS. In addition, NCHS is the only annual source of nationally aggregated data on the characteristics of the persons involved in these events.

## EMERGENCY WORKERS

Question. What efforts, if any, have been made, either at the CDC or through HRSA, to educate emergency workers (Fireman, Paramedics, etc) about AIDS and the risk associated with the transmission of the AIDS virus?

Answer. CDC has offered emergency workers and "first responders" technical assistance on prevention of AIDS virus transmission in three ways:

- Recommendations and guidelines published since 1981 in the Morbidity and Mortality Weekly Report have directly addressed precautions for a variety of health care and allied health professionals, such as providers of prehospital emergency health care (paramedics, emergency medical technicians, law enforcement personnel, firefighters, lifeguards and others).

- One of the Public Health Service educational videotapes is entitled "AIDS and Your Job - What You Should Know." The videotape was developed for police officers, firefighters, and paramedics and is still in circulation. The tape was originally released in 1984 .

- Limited technical assistance (offered by mail and over the telephone) to individuals and to local and State groups of emergency personnel is provided on a daily basis by CDC on prevention of HIV transmission.

## MINORITY AIDS EDUCATION AND PREVENTION PROGRAMS

Question. Given the disproportionate number of persons with AIDS who are black and Hispanic, would you agree that we should be increasing our efforts to provide AIDS education and prevention programs and services to the black and Hispanic communities?

Answer. We agree that providing AIDS education and prevention services to Black and Hispanic communities is a very high priority. In fact, we have substantially increased our commitment of resources in both this year and 1989. The 1989 budget requests over $25 million specifically to target AIDS prevention programs to minorities, an increase of $4 million over 1988 and about $18 million over 1987.

In addition, minority populations should also benefit from the $355 million proposed to be spent in 1989 on other AIDS prevention and education efforts, such as AIDS counseling and testing projects, national AIDS public information campaigns, State and local education projects aimed at the general public and high-risk populations, school health education programs, and pediatric AIDS prevention projects.

Question. Dr. Mason, how much are we spending in 1988 on specific AIDS activities for black and Hispanic communities? How much are you requesting in 1989?

Answer. CDC has earmarked $20,800,000 in FY 1988 for HIV prevention activities directed specifically to minority populations at risk. In FY 1989 it is estimated that $25,156,000 will be targeted to minorities.

## AIDS EDUCATION FOR DENTISTS

Question. What are your individual agencies doing to educate and train dentists about AIDS and AIDS infection control methods?

Answer. For the past three years, CDC has taken an active role in gathering and disseminating information that relates to the education and training of dentists and other dental health care workers about AIDS and AIDS infection control. A variety of information/education materials have been developed, and continue to be refined. In April 1986, CDC published infection control guidelines for dentistry; subsequently, CDC developed and widely disseminated the pamphlet, "Preventing the Transmission of Hepatitis B, AIDS, and Herpes in Dentistry." In August 1987, CDC further defined the recommendations for prevention of HIV transmission in health-care settings, which specifically included infection control practices in dentistry.

Currently, CDC is developing educational materials, in collaboration with a number of professional organizations and other Federal agencies. These activities include:

- A collaborative effort between CDC, National Institute of Dental Research, Food and Drug Administration, Veterans Administration, and the American Dental Association (ADA) to develop and produce an educational videotape series on infection control within the dental care environment.
- Development of additional curriculum guidelines for dental educational institutions in collaboration with the Health Resources and Services Administration.
- Supporting the ADA in printing and distributing a pamphlet, "Facts About AIDS for the Dental Team."
- Development of an infection control risk-management assessment package for dental health care workers, which will be disseminated in a joint effort with the Food and Drug Administration.
- Development of a fact sheet for broad distribution, about risks of infectious diseases in the dental care environment.

CDC will continue to provide technical assistance and consultation to States and public and private organizations upon request, and will continue to publish articles in major professional journals and the MMWR.

## DENTAL SERVICES FOR AIDS OR HIV POSITIVE INDIVIDUALS

Question. Are you concerned about the availability of dental services for those who are HIV positive or have AIDS?

Answer. Yes. It has been reported in the popular press, as well as a national survey conducted by a dental professional organization, that dentists have expressed concern about treating HIV positive or AIDS patients and many would refuse to treat them--out of fear of increased risk of transmission of AIDS, lack of knowledge about AIDS, and concern of losing other patients.

Question. What recommendations do you have for insuring that these services are provided?

Answer. CDC will continue efforts to encourage routine adoption of recommended infection control procedures for the dental care environment, and continue the efforts to allay unfounded fears about the risks associated with treatment of infected patients. If recommended infection control procedures are used routinely in a dental practice for all dental patients, then the risk of transmission of HIV can be greatly reduced for dental health care workers.

## HETEROSEXUAL STUDIES

Question. What kind of studies is the NIAID planning to conduct to acquire information about the rate of Heterosexual transmission? Dr. Mason, is the CDC planning any such studies?

Answer. CDC has ongoing studies on heterosexual transmission of HIV from infected hemophilia patients and IV drug abusers to their sex partners. In addition, CDC has awarded funds in FY88 to blood banks to expand studies of transmission between infected transfusion recipients and their partners. Additional funds for heterosexual transmission studies will be announced in an RFA to be published this spring.

## SUBCOMMITTEE RECESS

Senator CHILES. The subcommittee will stand in recess until 11 a.m. tomorrow, Friday, April 22, when we will meet in SD-192 to hear from the Alcohol, Drug Abuse, and Mental Health Administration.

[Whereupon, at 11:05 a.m., Thursday, April 21, the subcommittee was recessed, to reconvene at 11 a.m., Friday, April 22.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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FRIDAY, APRIL 22, 1988

U.S. Senate,
Subcommittee of the Committee on Appropriations,
*Washington, DC.*

The subcommittee met at 11:15 a.m., in room SD-192, Dirksen Senate Office Building, Hon. Lawton Chiles (chairman) presiding.

Present: Senators Chiles, Bumpers, Weicker, and Domenici.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Alcohol, Drug Abuse, and Mental Health Administration

### STATEMENT OF ROBERT L. TRACHTENBERG, DEPUTY ADMINISTRATOR

ACCOMPANIED BY:

DR. LEWIS L. JUDD, DIRECTOR, NATIONAL INSTITUTE OF MENTAL HEALTH

DR. CHARLES R. SCHUSTER, DIRECTOR, NATIONAL INSTITUTE ON DRUG ABUSE

DR. ENOCH GORDIS, DIRECTOR, NATIONAL INSTITUTE ON ALCOHOL ABUSE AND ALCOHOLISM

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET

### OPENING REMARKS

Senator Chiles. This morning we continue our hearings on the President's fiscal year 1989 budget request. Today's hearings are going to concentrate on the request for the Alcohol, Drug Abuse, and Mental Health Administration and the Health Resources and Services Administration.

I would like to first welcome our witnesses from the Alcohol, Drug Abuse, and Mental Health Administration: Mr. Trachtenberg, who is the Deputy Administrator, and the three Institute directors: Dr. Judd from mental health, Dr. Schuster from drug abuse, and Dr. Gordis from the Alcohol Institute.

Dr. Judd, we are particularly pleased to have you in your first appearance before the subcommittee.

The Alcohol, Drug Abuse, and Mental Health Administration deals with illnesses that threaten the well-being of millions of families, conditions that people sometimes have tried to conceal out of fear or shame.

The Institutes have done important work to bring these illnesses into the open, to move beyond the stigmas and look for answers and causes to their treatments. The Alcohol, Drug Abuse, and Mental Health Administration works in so many important areas: Alzheimer's disease, schizophrenia, depression, and the fetal alcohol syndrome, to name a few.

While we will touch on all of these in this morning's hearings, I would like to give special attention to another problem that concerns me greatly, and that is the problem of the epidemic of drug abuse that is ranging across our country.

I will be especially interested in learning more about the research the National Institute on Drug Abuse is conducting in the areas of drug abuse prevention and treatment and about Federal contributions to the actual delivery of drug treatment services.

Mr. Trachtenberg, and I am probably not pronouncing that right. My problem is I never learned phonics. They quit teaching that when they were teaching me, and so if I cannot memorize it I do not know about it. I answer for Chiles, Chillies, and many other things that my Cuban friends come up with. [Laughter.]

Let us get started, if you would summarize your statement. And as I said, I may have to run at some stage when the vote starts.

Mr. TRACHTENBERG. I would like to submit my formal statement for the record. You have already introduced the Institute directors and so I will not bother going through that. We do have a Department representative from the budget office, Mr. Dennis Williams, who is here as well on my far right.

Senator CHILES. He comes to several of these hearings.

### OPENING STATEMENT

Mr. TRACHTENBERG. The President's budget for fiscal year 1989 requests for ADAMHA $1.326 billion. This is a very impressive amount of money, but it is also a very impressive kind of problem that we face in this Nation in terms of the alcohol, drug, and mental disorders that exist.

From just an economic standpoint, both in terms of direct cost and indirect cost, these disorders cost our society over $250 billion annually. That is a number that we will be updating soon and I suspect that the figure will be considerably higher when the final reports are in.

And this does not include the pain and suffering that families and individuals experience. Sadly, it goes beyond that. About 1 of every 5 individuals in any given 6 month period will have a diagnosable mental disorder.

About 1.6 million adult schizophrenics will be suffering from schizophrenia in any given 6 month period. About 25 percent of the AIDS patients are IV drug addicts. About 6½ million Americans are drug addicts, either moderately or severely or extremely disabled due to their drug addiction or their drug use.

Alcohol-related problems kill in the neighborhood of 100,000 people a year, and alcohol-related problems are the leading cause of death for males under the age of 35.

So the costs of the problems that we face in ADAMHA and that this committee faces when deliberating on our budget are impressive, as is the size of the fiscal year 1989 budget that we are requesting today.

Indeed, Mr. Chairman, the budget is a reasonably good one for ADAMHA in our view. It permits us to fully fund our research grants. It permits us to have a new and competing grant level of approximately 500 grants. That number is close to the level we have averaged during the past 10 years. It will also permit about a 5.4-percent increase in the average cost of the grants.

In fiscal year 1989 we will be supporting about 1,654 research grants. That is a new high point in terms of the total number of grants that ADAMHA has ever supported.

In addition to our research project grants, the other area of highest priority for ADAMHA is our research centers. We will be funding 50 multidisciplinary centers of excellence in fiscal year 1989. We will be able to fully fund those centers.

Of course, there are always tradeoffs, and by dealing with the high priorities that I just mentioned we will have less money to spend in new starts and other research mechanisms, in cooperative agreements and in contracts.

But we think the tradeoff, the reduction of $7 million in new starts, is acceptable because we can fund the highest priority areas of research project grants and the centers.

Mr. Chairman, the knowledge base that has been developed in these areas, as you noted in your opening statement, is exploding, is exquisite, and is impressive. This committee has helped, through its support, ADAMHA to reach the discoveries that we are discussing.

The areas of neuroscience, genetics, and treatment efficacy are exploding. The ability to develop new analytical capacities in neuroscience is going to yield tremendous benefits to the public. The fact that there are new research techniques, advanced computer technologies, better imaging techniques, new skills in molecular biology—all run to the ultimate benefit of society.

In addition, we are poised to learn more and to mount a major effort as we approach what we refer to as the decade of the brain. As we build this knowledge base in neuroscience, we are going to learn much about the brain, how the brain functions, and, more importantly in some respects, how it dysfunctions and how that dysfunction affects areas that involve alcohol, drug, and mental disorders.

We will learn from neuroscience studies how the environment impacts on brain dysfunction and thereby causes these disorders.

The dividends are high—the dividends will be extensive in the area of clinical applications.

Senator CHILES. I probably should interrupt you there. We are in the halfway part of this vote and I think I had better run and vote.

[A brief recess was taken.]

Senator WEICKER [presiding]. The committee will reconvene.

As I understand, Mr. Trachtenberg is in the conclusion of his statement. So why do you not proceed.

Mr. TRACHTENBERG. Senator, I was talking about the size of the budget and its impact on the many people in need who suffer from alcohol, drug, and mental disorders. I was talking about the investment in research and how beneficial it has been and will continue to be to the public.

I was touching on some of the clinical applications that have been developed. In that respect, I was referring to the fact that the National Institute on Alcohol Abuse and Alcoholism is developing an objective marker of alcohol consumption that will assist greatly in the diagnosis of alcohol-related problems.

They are also continuing to develop new information on the inheritability of alcoholism as a disease, particularly in certain types of alcoholics.

NIMH is about to embark on a major public awareness campaign involving depression, which is an extremely treatable disease. Their program, called DART, will bring, we believe, thousands of people who are in need of treatment into treatment, that will be a major accomplishment.

NIMH is also developing a positive diagnostic marker for Alzheimer's disease. In the drug abuse area, NIDA is developing new pharmacologic approaches to dealing with opiate addiction. These drugs will be longer acting and will be more effective.

In the area of AIDS, NIMH is a leader in the entire area of the neurobiology of AIDS, looking at the neuropsychiatric aspects including the dementia that occurs in a considerable number of AIDS patients.

NIDA is playing a very pivotal AIDS role by focusing on IV drug addicts and their significant others in terms of not only getting the addict into treatment, but also changing their risk-taking sexual behaviors as well as their dangerous needle sharing practices.

Until we can get all IV drug addicts into treatment, we have to get them to use clean needles. But the ultimate goal here is to get people into treatment.

The role of ADAMHA is important in many areas, and we believe that there has been tremendous expansion of knowledge in all of these areas.

In the nonresearch areas there is an $18 million increase in our homeless activities in the fiscal year 1989 budget. The Office of Substance Abuse Prevention, which is a new entity that was developed as part of the Anti-Drug Abuse Act of 1986, will be able to meet its commitments in fiscal year 1989, and we are pleased about that.

In the area of the block grants, both the alcohol and drug treatment rehabilitation block grant and the alcohol, drug, and mental health services block grants show increases.

PREPARED STATEMENT

In the interest of time, I would like to conclude at that point, Mr. Chairman, and turn it over for any questions that I or the Institute directors who are with me today may be able to answer for you.

[The statement follows:]

# STATEMENT OF ROBERT L. TRACHTENBERG

I am pleased to appear before you today to discuss the President's fiscal year 1989 budget request for the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA). We believe that ADAMHA has fared well in this year's budget deliberations and has been provided a budget that reflects the Administration's concerns with the problems that we are attempting to address.

When we try to measure, in terms of dollars, the annual cost of the health problems associated with ADAMHA programs, the total becomes an astronomical number that is hard to grasp -- about $249 billion. This enormous cost includes health care expenses, reduced productivity, accidents and violence related to alcohol and drug abuse and mental illness, as well as other indirect costs. But even this sum does not account for the immeasurable personal suffering attributable to these diseases. It is clear that the resources we devote to dealing with these problems address a major national need.

While drug abuse continues at an unacceptably high rate, there are some encouraging signs of progress in our latest annual survey of drug use by high school seniors. The 1987 survey showed continuing declines in the use of many drugs by seniors. I am particularly happy to note the first substantial decrease in current use of cocaine - a drop of one-third in a single year, from 6.2% to 4.3% The survey also showed an increased awareness among our young people of the dangers of even one or two uses of cocaine. Now nearly half of the seniors (48%) see "great risk" in trying cocaine compared to only one-third in the 1986 survey. We believe these developments reflect the success of activities at the Federal level and in communities all across the nation in driving the point home that drug use can result in serious harm to one's health.

Unfortunately, for the third year in a row, the high school senior survey found no change in alcohol abuse by these youngsters. Some 66 percent still reported use within the last 30 days. Five percent were daily drinkers, and more than 37 percent reported at least one occasion of heavy drinking within the past two weeks - that is, they had five or more drinks in a row.

The toll which alcohol abuse and alcoholism takes on our health and, collectively, on our society clearly has roots as early as the high school years, or even before. Health problems related to alcohol abuse continue to be a major killer in the U.S., taking about 100,000 lives annually.

Our recent epidemiological surveys indicate that one out of every five Americans has a diagnosable mental health problem during any six-month period. We know that between 9 and 10 million have a depressive illness, and that 1 and 1/2 million suffer from the most intractable mental illness of all -- schizophrenia.

While AIDS activities are consolidated into a single PHS account in FY 1989, it should be noted that ADAMHA is very involved with and concerned about the problem of AIDS. Use of IV drugs occurs in one quarter of all persons with AIDS and is also responsible for a major portion of heterosexually transmitted and pediatric AIDS cases. Research also shows early infection of the nervous system causing behavioral changes in individuals who are seropositive for the AIDS virus.

Increasingly in recent years, ADAMHA has successfully focused its attention upon the strengthening of its research programs. This has come at a time when the entire field of ADM research has been expanding at a rapid rate. Since ADAMHA is involved, in large part, with diseases of the mind, our research has profited greatly from the explosion in the "brain sciences". ADAMHA has been at the forefront of neuroscience, providing leadership as well as being directly involved in some very important breakthroughs, many of them with clear, immediate practical applications.

NIMH research has led to several exciting discoveries which have great promise for the future. In the basic and preclinical area, studies focus on identifying the nature and extent of structural change in the brains of Alzheimer's patients as well as developing a comprehensive approach to the neurochemical aspects of the disease. A neurochemical deficit involving the cholinergic system has been identified, and the anatomical site of the neurochemical loss has been identified in the nucleus basalis. Investigation is now being directed toward other neurotransmitters that may also be implicated in Alzheimer's. In important new developments, a protein specific to Alzheimer's and a specific blood platelet abnormality have been identified. These show great promise in the development of a positive diagnostic marker for the disease.

In addition, several areas of fundamental research in the neurosciences are advancing our understanding of how the brain works, and consequently have significant implications for mental illness. The study of events at the junction between nerve cells, the synapse, has begun to reveal details of how communication takes place between nerve cells. A phosphoprotein, Synapsin I, is the subject of intense interest because it appears to play a key role in the neurotransmitter release process. Synapsin I also offers a new methodological approach to the study of presynaptic drug actions because its ubiquitous and presynaptic location in nerve terminals makes it a unique marker for anatomical and biochemical studies. Research findings such as this, leading to a detailed understanding of neural events involved in nerve transmission hold great promise for the development of new drugs with great specificity for treatment of mental disorders, as well as for a basic understanding of brain function.

Other studies by our intramural scientists -- in this case in the National Institute on Alcohol Abuse and Alcoholism -- have shown that it may be possible in the near future to use a blood test to identify persons with alcoholism -- even when they have not had a drink for a long time. Working in collaboration with scientists at the University of Chicago, the investigators based their studies on animal research which had shown that the activity of two blood enzymes - adenylate cyclase and monoamine oxidase -- are changed by chronic consumption of alcohol. Testing for this difference in human subjects, they found it to be 75 percent accurate in distinguishing alcoholics from people who do not have a drinking problem. These developments could provide an effective means for identifying individuals who are suffering from alcohol abuse when they seek care for other health problems.

Recent studies of brain wave patterns of abstinent alcoholics has revealed both sensory and cognitive electrophysiologic deficits in these patients as compared to non-alcoholics. In an effort to determine whether these effects were related to previous alcohol abuse, scientists examined brain waves in the young, alcohol-naive, sons of alcoholics. They found reliable electrophysiologic differences in the brain activity of these high-risk youth. These findings suggest that while some brain deficits observed in abstinent alcoholics appear to be the consequence of alcohol and/or nutritional related events, other deficits may antecede the development of alcoholism and may represent a predictive factor. The application of new genetic techniques in the study of such markers of predisposition may now lead to the identification of genes contributing to the risk for alcoholism and to the identification of genetic subtypes of alcoholism.

Significant progress also has been made in the National Institute on Drug Abuse in understanding how cocaine works in the brain. It has been known for some time that dopamine plays a major role in cocaine's powerful reinforcement action, and in the reward users get from the drug. Scientists at the Addiction Research Center of NIDA have shown that these effects may be due to cocaine's ability to bind to the dopamine transporter mechanisms in membranes, thereby prolonging the action of the neurotransmitter. This discovery may provide important leads in the search for new and more effective treatment and prevention modalities for cocaine abuse.

A traditional treatment for depression has shown some success in reducing the craving of cocaine abusers. The tricyclic anti-depressant desipramine significantly reduced weekly cocaine use in a patient population studied by NIDA-funded researchers.

The leadership ADAMHA has been providing is no better exemplified than in two recent documents setting forth national research goals and agenda of national scope and importance. First is the report from the National Advisory Mental Health Council on a National Plan for Schizophrenia Research which documents the extent of this significant national public health problem and the development of a national research effort designed to identify its causes and develop effective more treatments. It is clear that schizophrenia is multifaceted -- in its origins, manifestations, course, and treatment. Hence, the National Plan deals with research across a broad spectrum of the biological and behavioral sciences -- with topics as varied as genes, viruses, neurotransmitters, brain structure, emotion, perception, and human behavior. It is the special relationship of research in ADM disorders with the much needed body of research in the neurosciences that makes the development of the second report -- The Decade of the Brain; Neurosciences Report -- so timely. This report sets forth the dramatic advances in the basic neurosciences and in understanding the function of the brain as well as identifying promising areas of effort in this scientific frontier. To accomplish the agendas of both the Schizophrenia Plan and the Decade of the Brain will require a concentration of effort and resources over the coming years.

I would like to turn now, with this background, to directly address some of the highlights of the fiscal year 1989 ADAMHA budget before us today. While they demonstrate the priorities in our budget, it should be noted that three programs - mental health clinical training, community support programs, and protection and advocacy - are proposed to begin a three year phase over to state and local resources in fiscal year 1989.

First, with regard to the research programs of such importance to the agency, we find that there is an increase of more than $22 million over the 1988 appropriation. With this increase we will be able to support essentially the same number of research project grants as in 1988 -- about 1,650. We have been able to provide a 5% increase in average cost for these grants which will allow us to fund them at the levels recommended by the national Advisory

Councils. The request also supports all of the agency's 50 research center grants as well as provides $7 million for new awards in other research mechanisms. The intramural programs maintain their current level of operations with an allowance of additional funds to the NIMH program for acquisition of sophisticated equipment necessary to implement initiatives associated with neuroscience and schizophrenia.

This budget also assures that the momentum begun with the 1987 supplemental of $250 million for substance abuse initiatives continues in fiscal year 1989. The total budget for drug activities in ADAMHA increases from $523 million in the 1988 appropriation to $596 million. This increase of 14% shows the high priority that the Administration places on these efforts.

Also worthy of specific mention is the significant increase that the budget provides for ADAMHA programs dealing with the nation's homeless problem. The 1988 appropriation designated $18 million for these activities while the President's budget for 1989 more than doubles this total to over $37 million. We believe that this current plight of too many of our citizens is a very serious issue that must be dealt with now.

Finally, some reference to Saint Elizabeths Hospital would be appropriate here.

On October 1, 1987 the Department of Health and Human Services transferred responsibility for mental health services to D.C. residents from Saint Elizabeths Hospital (SEH) to the District of Columbia government in accordance with provisions of Public Law 98-621, The Saint Elizabeths Hospital and the District of Columbia Mental Health Services Act.

At this juncture, we are engaged in transition activities but are no longer involved in SEH operations. The 1989 appropriation request totals $24,000,000 to provide for the annual subsidy payment as authorized by provisions of Public Law 98-621. These payments are to assist the District in its assumption of full responsibility for operation of the hospital through the Fiscal Year 1991 completion of the Financial Transition Period specified in the transfer legislation.

I will be glad to answer any questions that you may have.

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## BIOGRAPHY OF ROBERT L. TRACHTENBERG

Robert L. Trachtenberg was named the Deputy Administrator of the Alcohol, Drug Abuse, and Mental Health Administration (ADAMHA), in May 1979. He has served as Acting Administrator on three separate occasions when that post was vacant -- from June 1980 to January 1981, from September 1983 to July 1984, and from November 1985 to July 1986.

As ADAMHA's Deputy Administrator, Mr. Trachtenberg shares with the Administrator responsibility for administering and coordinating Federal programs and activities to improve understanding, prevention, and treatment of alcohol, drug abuse, and mental health disorders. ADAMHA is composed of three Institutes: the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (NIDA), and the National Institute of Mental Health (NIMH). The newly created Office of Substance Abuse Prevention is located within the Immediate Office of the Administrator.

In addition, Mr. Trachtenberg is directly responsible for supervising the internal management of the Office of the Administrator to assure responsiveness to workload requiremnts, and developing and implementing management and program systems and procedures to comply with agency policy priorities. Also, he maintains continuing oversight of Institute activities and assists the Institute Directors develop sound management and program policies.

For a brief period, between October 1981 and July 1982, he was called upon by the Secretary to establish and administer the Department's multi-faceted block grant and discretionary funding programs. This included closing out much the operation of the Department's Office of Community Services and implementing creative fiscal, audit, and grants managment practices under the new provisions of President Reagan's Economic Recovery Program.

Prior to joining ADAMHA in 1979, Mr. Trachtenberg had been an Associate Commissioner for Hearings and Appeals, and Chair of the Appeals Council for the Social Security Administration since 1975. In this position he was responsible for providing program and management direction over a decentralized hearings program and centralized appellate system. The Office for Hearings and Appeals is one of the largest systems of administrative law judges (650) in the Federal Government. With the exception of the Department of Justice, it employes more attorneys than any other Federal agency.

From September 1973 to January 1975, Mr. Trachtenberg was Deputy Assistant Secretary for Grants and Procurement Management, Office ofthe Secretary, Department of Health, Education, and Welfare. He was responsible for developing, promulgating, and enforcing all procurement and grant regulations and policy for the Department, including cost and audit policy, and minority business. Also, he supervised contractor protest procedures; and monitored and evaluated performance of more than 200 grant and procurement offices throughout the Department.

Mr. Trachtenberg served as Deputy General Counsel, Office of Economic Opportunity from August 1967 to September 1975, where he specialized in procurement and grant law as well as legal and business management, and supervised the Agency's investigative operation.

A graduate of Fairleigh Dickinson University (B.A. 1957) and the New York Law School (LL.B. 1959), Mr. Trachtenberg began his Federal career in August 1960 with the Department of the Army. He served the Department of the Army in various positions, including four-and-a-half years in the Judge Advocate General's Corps. He is admitted to practice law in New York State and Washington, DC.

Born in Brooklyn, New York on February 17, 1937, Mr. Trachtenberg has received numberous awards and honors. They include: two Presidential Senior Executive awards (SES Meritorious Rank 1980 and SES Distinguished Rank 1982) the 1985 Rogert W. Jones Award for Executive Leadership, the 1986 Philadelphia County Medical Society Annual Humaneness in Medicine Award, the 1974 William A. Jump Foundation Recognition Award, three DHHS (HEW) Secretarial Citations (1975, 1977, and 1987), and two Social Security Administration Citations (1976 and 1978). Also, he was a member of the prestigious Administrative Conference of the United States 1975 - 1979.

He is married and has four children.

## PROTECTION AND ADVOCACY

Senator WEICKER. Thank you very much.

Mr. Trachtenberg, last year I strongly objected to the administration's proposal to cut the funding for protection and advocacy programs [P&A] for the mentally ill as a first step toward phasing the program out. This committee and the entire Congress rejected that proposal and in fact provided a small increase in 1988.

Now again this year, a cut of $2.5 million is proposed in the Protection and Advocacy Program in the budget. The justification states: "The Protection and Advocacy Program will be phased over to ongoing State responsibilities by reducing Federal funding each year beginning in fiscal year 1989."

Why would you think this should be a State responsibility when it was the States in the first instance that were not adequately monitoring and protecting the patients' rights?

Mr. TRACHTENBERG. Well, I think what the justification is referring to is what the source of the money will be. The protection and advocacy laws now are on the books. We think there is adequate money in the block grant, particularly the mental health part of the block grant, to deal with protection and advocacy.

I received the brunt of your displeasure this last year, Senator, and I certainly heard what you were saying. There is a smaller reduction this year than last year, so maybe your voice is being heard in this area.

But I think it is an area of honest disagreement, sir.

Senator WEICKER. Well, so that the history of the matter remains straight, I negotiated very hard with the administration to have protection and advocacy become the law for the mentally ill. And literally within 1 year after an agreement was arrived at and the administration signed aboard the P&A for the Mentally Ill Act, you turned around and you figured: Now we can go ahead and kill it via the funding route.

And I just want everybody to know that this has been a hallmark of this administration toward those who are less fortunate. And I think it is a disgrace.

Now, you know as well as I do that as far as the block grant is concerned, that money is for services for the mentally ill, for alcohol, for drugs. Those are for services.

It is not meant for protection and advocacy, and I see no reason why it should come out of the services to be rendered to persons that have whatever the affliction is. I do not see why the money should come out of there.

It is just like, I defended all of you people when they tried to go ahead and pay for the war on drugs, if you will recall 2 years ago, by taking it out of mental health and alcohol abuse moneys. I said, if you want a war on drugs, get the money and pay for the war on drugs; do not take it out of this other area.

And so I do not think that that is an answer in the sense of the block grant funds being available to do the job. On the other hand, I will respond to your wish in the sense that you may rest assured that this is not going to be funded out of existence.

We will again, I would imagine, if I can prevail upon the chairman—and the chairman has been very supportive, even to have a small increase. It is the only protection these people have. It is the only protection they have, and I have got to tell you, if you sat through the hearings that we conducted on the way the mentally ill of this Nation are treated, God help them.

I do not know how they have lasted as long as they have—of course, many of them have not—without the advocacy of such a unit.

Mr. TRACHTENBERG. I do not think anyone questions, Mr. Chairman, the validity or the merits of the legislation itself.

### TREATMENT BLOCK GRANT

Senator WEICKER. Yesterday when the Assistant Secretary for Health, Dr. Windom, was here, there was a difference of opinion about how much of the Federal drug treatment funds have been obligated and spent in Connecticut. I have since checked with the Connecticut Alcohol and Drug Abuse Commission and the Commission informs me that all of its Federal allocation has been obligated, and that one-half has actually been spent.

This was not the same information I was given by Dr. Windom. I do understand that there is some concern about why many States have not obligated and spent their allocations of Federal drug treatment moneys, and I share that concern and would like to know what ADAMHA is doing to identify obstacles that States may be encountering in spending the money, and what is ADAMHA doing to assist States in overcoming these obstacles.

Mr. TRACHTENBERG. Well, there has been an enormous amount of discussion around the drawdown issue, and I want to clarify it. That is what the issue is. The States, under the fiscal accounting rules, are allowed to drawn down 3 days in advance of their actual needs.

We have two major block grants: the alcohol, drug, and mental health services block grant, and the fiscal year 1987 funds for this program are probably drawn down by the States about 80 to 90 percent at this time. The drawdown, in other words claiming the money from us, is slower for the newer alcohol, drug treatment, and rehabilitation block grant, the program that you are referring to now, Senator.

I think that is a function of the fact that the States were a little slower in starting up. They were concerned whether this was going to be 1 year money or 2 year money. The States had to build additional capability. I think what you are seeing, as in Connecticut, is the fact that they have made commitments to spend the money, but there is going to be some time factor in when they pull that money out of the Federal Treasury.

A problem is that the money has 2-year availability, so it has to be spent within the next 6 months. This is an issue that many of the States are very sensitive to now, and we have seen a major increase in the drawdown since congressional members have shown some particular concern about this in New York and in other areas.

So I think it will eventually come around. I think there has been a confusion between the States' obligating the funds and the issue of the States drawing down the funds. My sense is that they are probably pretty far along in obligating it and now they have to start moving in terms of spending it.

Senator WEICKER. One particular problem which many States have faced, including Connecticut, is actually acquiring the buildings and space in order to provide drug treatment programs.

What efforts is ADAMHA making in order to provide treatment space as well as treatment slots? And are we training enough counselors and clinicians to provide the services to go along with the anticipated increase in services?

Mr. TRACHTENBERG. These are serious issues. They are issues that the States are facing. We think in terms of the level of support provided by the $162 million that represents the ADTR block grant. In terms of methadone maintenance, there probably is a reasonable amount of space and facilities available.

I think much more expansion beyond that and we are talking about a serious facilities need.

The training is also an important issue and, as we talk about larger expansions in drug treatment, particularly related to IV drug abuse and the AIDS problem, we have to consider training as an important element of any expansion.

### ALZHEIMER'S DISEASE

Senator WEICKER. Dr. Judd, would you please update the committee on the latest developments in the research on Alzheimer's disease.

Dr. JUDD. Yes, Senator; this has been a very active and good year for us in this regard. We have been focusing on the development of a diagnostic profile to enable clinicians to diagnose Alzheimer's patients before autopsy. Currently the only way we can make a diagnosis with any certainty is at autopsy.

A protein specific to Alzheimer's disease, as well as a blood platelet abnormality have been identified. These developments show great promise in the development of a positive marker for the disease. We feel these will be of great benefit to both the patient and to the family.

In addition, NIMH scientists have been very involved in identifying the deficit that occurs in the neurotransmitter system of the Alzheimer's patient, which is in the cholinergic system. This finding has been used in directed scientific inquiry into better and new medication to correct the deficit.

Finally, we have been doing clinical surveys in both patients and their families and have found that the stress that occurs in families who are responsible for taking care of an Alzheimer's victim is enormous.

Researchers have found that 40 percent of the spouses of an Alzheimer's victim are suffering from serious treatable clinical depression. In addition, the stress is so high that it actually is affecting the immune system by suppressing it and making caregivers vulnerable to disease and illness.

We are now in the process of developing new service research models to both deal with the family and with the patient, because we now see we are dealing with two patients in this situation: the individual who is afflicted and the person who is responsible for giving care to them.

Senator WEICKER. How much money are you requesting for this research in the research that you are doing in fiscal year 1989, and how does that compare with 1988?

Dr. JUDD. Approximately one-half of the NIMH budget for the mental disorders of aging goes to research on Alzheimer's disease. This means that in fiscal year 1988 we expect to spend $87 million on Alzheimer's disease and in fiscal year 1989 we hope to spend $9.3 million. This includes three of our five geriatric clinical research centers which focus almost exclusively on Alzheimer's disease. But this only represents that component of our research program focused specifically on clinical care delivery and clinical research on the Alzheimer's patient.

The proposal increases the amount of resources for neurosciences. This is the area where much of the research on the basic mechanisms of Alzheimer's disease goes on.

Senator WEICKER. What about the National Institute on Aging? Does that get into this act also?

Dr. JUDD. Indeed, the National Institute on Aging has a program on Alzheimer's disease. They are the Institute that funded the Alzheimer's centers.

Senator WEICKER. Senator Domenici.

### SCHIZOPHRENIA RESEARCH PLAN

Senator DOMENICI. Thank you very much, Mr. Chairman.

Let me thank all of you for being here and for the work you do. I would like to address a few questions first to Dr. Judd, if I may.

Senator DOMENICI. Thank you, Mr. Chairman. In my introductory remarks on schizophrenia I would like to make two points.

I hope no one misinterprets this first observation, because it is an attempt to compare the incidence of schizophrenia with other serious illnesses, and I do it as a preamble for the record. I do it only to establish the importance of the schizophrenic research plan relative to moneys being expended in other programs.

And so I should say as a preamble to my question that schizophrenia is twice as common as Alzheimer's disease, five times more common than multiple sclerosis, six times more common than insulin-dependent diabetes, 50 times more common than cystic fibrosis, and 60 times more common than muscular dystrophy.

And the minimal estimate for annual cost of treatment for schizophrenia is that it exceeds $7 billion. Many people do not even know that at its peak schizophrenic victims are so disabled that they are put in hospitals. The estimate is that patients with schizophrenia occupy over 30 percent of the Nation's mental hospital beds, over 100,000 beds, on any given day.

And that is without other treatment that we are not able to put into this equation. And so when I allude to the national plan and the need for that funding, I do not do so on the basis of picking something that I happen to be interested in. I think, relatively speaking, that it deserves attention. In any way that we as Americans normally look at things, I would say this is a big, big problem, and it deserves attention.

I am aware of the fact that the President in his budget request for the National Institute of Mental Health has requested $271.8 million for all of the research within NIMH, excluding AIDS.

I am also aware of a very exciting proposal that you and many around the country have been working on for a long time, called the national plan for schizophrenia research which, while not separate and distinct from your work, would be to some extent integrated into NIMH. It would focus on a multiyear research effort to address this very serious illness that is so prevalent in the United States and has such devastating effects.

How does the amount that the President has requested for NIMH in fiscal year 1989 compare with the resources that are recommended for the schizophrenic plan?

Dr. Judd. The plan, which is right here, Senator, is the national plan for research on schizophrenia. And as you indicated, this has been a major scientific effort involving 160 scientists in this country.

The scientific community, the Institute, and the advocacy groups feel the time is ripe for a major scientific attack on what has been one of mankind's most baffling and disabling disorders. In regard to the question you asked, the Institute would need $57.8 million to fully implement the national plan for schizophrenia research in fiscal year 1989.

What is available in the President's budget for 1989 is $3.6 million.

Senator Domenici. $3.6 million?

Dr. Judd. Yes, sir.

Senator Domenici. So the coalition of mental health groups, a very diverse group now brought together, has prepared and recommended an NIMH research budget of $400 million for 1989, excluding AIDS. Obviously, Dr. Judd, you are part of the administration, and I am not trying to put you on the spot. I would, however, like your evaluation for our subcommittee of what additional initiatives NIMH would undertake if the resources recommended by the national coalition were appropriated?

Dr. Judd. Yes, sir; there were eight panels in this report, each of them with a series of recommendations for what we feel is a rational scientific attack on schizophrenia and on all serious mental disorders, and one that is achievable within a finite period of time.

With these resources we would fund an additional 97 project grants in clinical and neuroscience research relating to schizophrenia. In doing so our payline in this area would only be increased to 170. We could expend a considerable part of that $58 million even this fiscal year.

In addition, we would under the plan initiate new research centers in serious mental disorders, new centers in the neuroscience of serious mental disorders. We would be creating a series of research resources that would be focusing on mental disorders. That is, imaging centers, a gene bank, and an expansion of the brain bank program that we are operating with the National Institute on Neurological and Communicative Disorders and Stroke.

The plan would also provide resources for much needed equipment. Currently the NIMH does not have a budget line item for equipment. The mental health research field is entering a phase budget where high technology scientific equipment is required if we are to take advantage of the enormous scientific opportunities that exist. The national plan states that research is being nampered by the inability to direct significant resources to the purchase and replacement of sophisticated equipment.

I can assure the committee, that if you are asking the question, could we use this money well and spend it for outstanding science at the cutting edge, I can say, yes, we can.

Senator Domenici. I note that the chairman has arrived, and although I have a few more questions, I am not perhaps as pressed for time as he is today. Would you want to proceed, Mr. Chairman?

Senator CHILES [presiding]. Go ahead, Senator Domenici.

Senator DOMENICI. Thank you.

Let me say that I know that we are tight on money up here. But frankly, I have not seen in the area of research on serious mental illness such a comprehensive plan to attack a major health problem. While I am no expert, I have been, for the last 4 or 5 years, and will continue for as long as I am around here, to make this a high priority in this country, because I think we have literally ignored this tremendous area called mental illness, serious mental illness, for far too long.

This research plan is relative to other illnesses and diseases, relative to the pain and suffering that is going on out there, and also relative to the potential for improving the well-being of our people.

I think we have underfunded this effort. Having said that, I have not seen a plan in an area as difficult as this so well prepared in advance and so well thought out on a multiyear basis as the schizophrenia national research plan. And I compliment everyone regarding it.

I truly believe that it would be a shame if we did not begin to implement it, if not in toto, at least substantially.

### HOMELESS BLOCK GRANT

Now, having said that, let me ask about the ADAMHA block grant for the mentally ill homeless. First, I am fully aware that the $43 million that we appropriated as part of the comprehensive homeless assistance bill was somewhat experimental in terms of where we placed the administration of various components.

But I am amazed as I look at the States that have applied for the block grant for the mentally ill homeless, that a number of States even today have not yet received their block grants. I am not critical of ADAMHA.

I think that perhaps they have not applied correctly, or they have found that the grant is not to their liking. But clearly, I think we have to know why and need an update on which States have applied and received the money, which have not, and your assessment as to why so many States, including some very large States and some that have been heavily involved in long-term planning for the mentally ill, have not yet received their money.

I do not know that you want to answer the question now, or want to supply us a detailed evaluation for the record. Whichever you prefer, is fine.

Mr. TRACHTENBERG. Senator, I would love to be able to answer, except I do not have that information. I would like to be able to supply it for the record.

[The information follows:]

*Status of MHSH block grants as of May 4, 1988*

| | |
|---|---|
| Applications received | 49 |
| Awards issued | 44 |
| Dollars awarded | $34,563,905 |
| Applications awaiting scheduled review | [1] 1 |
| Applications pending award | [2] 1 |
| Applications pending revisions | [3] 3 |

[1] North Carolina.

[2] Mississippi.

[3] California, Delaware, and Puerto Rico.

Note.—Applications have yet to be received from Hawaii, Maryland, and New Mexico.

Mr. TRACHTENBERG. I frankly was not aware that there was a problem in terms of slowness, either in our funding——

Senator DOMENICI. Well, I can tell you that California, Hawaii, Maryland, Virginia, Texas, Wisconsin—a pretty healthy group of States for starters—have not yet received the block grant money.

And we all take great pride that block grants get out to the States quickly. At least we normally say that, but it has not seemed to work this time.

Mr. TRACHTENBERG. We have done very well in the ADM block grants. I would have to look into that and find out whether the problem is churning up the States a little bit or back in Parklawn. But I will find out.

Senator DOMENICI. I think the reauthorization of the Stewart B. McKinney Homeless Act is on a fast track up here, since many of the programs expire. I think we probably are going to reauthorize this comprehensive and omnibus bill.

And let me say to you that I think we ought to have an assessment as quickly as you can for the record, if the chairman does not object, as to what we might do better as we put together the reauthorization of the mentally ill component of that bill as it applies to NIMH.

And I would hope that you would be extremely frank if you think the funding should be administered elsewhere or that we should coordinate it differently. I think the subcommittee would like to know.

Mr. TRACHTENBERG. I will be pleased to provide that information.

## STATE MENTAL HEALTH PLANNING

Senator DOMENICI. A very small item I would like to discuss is State mental health planning grants. Those who are supportive of moving ahead with mental health treatment have long said that with deinstitutionalization the big missing link was the lack of State plans to implement the delivery of mental health care.

Last year, with the marvelous help of the two Senators who are here, for the first time we funded at $5 million these State mental health planning grants. Each State gets the money, and they are to proceed to develop a State plan.

Could you tell us if the fiscal year 1988 funding has been awarded to the States so that these mental health planning activities can get underway? And for the record, could you provide the subcommittee with a brief summary of the activities undertaken by the States under their comprehensive State mental health planning grants?

Could you answer the first question as to whether the fiscal year 1988 funding has been awarded to the States so that they can start the planning process? Does anybody know the answer to that?

Dr. JUDD. I will answer that, Senator Domenici. At this point, all but six States have applied for the grants and we expect those to come in any day now. The money has gone out to all but those six States.

NIMH has provided leadership to this program through a number of activities. The Institute has held a national conference and a regional one with the States to outline for them what a comprehensive mental health plan should be. We have now developed a model plan for a comprehensive community based mental health system and that has now been disseminated to all the States. We are to provide technical assistance concerning needs assessment, consumer participation, interagency coordination, and evaluation.

The response from the States, I might add, has been very positive.

Senator DOMENICI. Very positive, you say?

Dr. JUDD. Very positive, yes, sir. And they are excited about it. They feel it is the right thing to do, the right direction in which to go. And we are working with them very closely.

Senator DOMENICI. Mr. Chairman, I have a number of other questions I will submit for the record.

### DRUG RESEARCH BUDGET

Senator CHILES. Mr. Trachtenberg, I am concerned about your budget request for drug abuse research. We hear a lot about the President's commitment to the war against drugs, but your 1989 funding request is below 1988 levels. I am told the lower request is the result of a decision to distribute 1989 funds between Institutes on the basis of 1988 new and competing grants.

But the National Institute of Drug Abuse did not have much money for new grants in 1988, so it was working off of a low base. If we are to fight against drug abuse and make it a top priority, why are we cutting the funding for research grants?

Mr. TRACHTENBERG. Well, it is certainly an area that we are very concerned about, Mr. Chairman. It starts in 1987 when the large increase in research dollars were appropriated as part of the Anti-Drug Abuse Act.

These 1987 dollars were intended to go for 2 years but the Congress decided, no, that is going to be for 1 year of funding and we will deal with 1988 separately. This generated a large amount of commitments in the following year, in fiscal year 1988. What happened then was that the Senate wanted to add new dollars in 1988 to support the 1987 level of new additional research grants in drug abuse as well as the large commitment base.

That went to conference with the House, which wanted to hold the line at the 1987 total level, which, due to the large base, would result in fewer considerably new grants. The House version was the result of the conference. In the end NIDA met the very large amount of commitments, but wound up with a very small number of new grants that could be funded in 1988 or 1989.

Our policy in 1989 was first to maintain the same proportion of new grants in the Institutes as in the 1988 appropriation. Well then, why did I not reallocate funds to NIDA, in effect taking them away from NIMH or NIAAA to increase NIDA's new and competing a reallocation would have violated our time-honored policy of stabilized funding, especially in a budget that was trying to just maintain the current level in 1989.

To have taken away from NIAAA or NIMH really would have been taking from the poor to give to the poorer, and it just did not make good sense, despite the obvious importance certainly of the drug initiative.

NIDA really got caught up in the impact of the very large numbers of dollars in 1987. They were, therefore, constrained in terms of new starts in 1988 and 1989.

Senator CHILES. Well, I think that it is a little confusing how that goes toward stabilization, if you have got one group that is shrunk.

Mr. TRACHTENBERG. But then there would be three Institutes that were not stabilized.

### INFANTS BORN TO ADDICTED MOTHERS

Senator CHILES. Dr. Schuster, in Florida I hear a lot about the tragedy of cocaine babies, infants who are born low birth weight and sometimes brain damaged or malformed, by mothers hooked on cocaine. Broward County has had a fivefold increase in the number of cocaine babies born in its hospitals last year.

We included language in the Senate report on the 1988 continuing resolution urging the Department to establish demonstrations for female drug abusers to encourage treatment prior to and during their pregnancy. The demonstrations were to include treatment, assessment, and referral, prenatal care, vocational services, and child care.

Give us an update, if you will, on what actions the Department is taking to carry out that report language.

Dr. SCHUSTER. First of all, sir, I would like to say that we share the Nation's great concern with the problem of infants who are born to addicted mothers.

One of the major problems we have in this area is that mothers who are using a drug rarely, if ever, are using only a single drug. As a consequence, it is difficult to attribute any abnormalities in the offspring to any specific drug.

For that reason, we have carried out a great deal of animal research in this area. And I would simply like to call your attention to the fact that we have been able to replicate in animal studies—and I have here a brain scan from such an animal showing the hyperactivity in a rat that is the equivalent of the age of an adolescent, born to a mother that was treated neonatally with cocaine at the time that this rat pup would have been in the equivalent of the 6th to the 9th month of pregnancy in humans.

At adolescence, when they were sacrificed, on the left here—all you have to do is look at the difference in color. This is a measure of neuronal activity, and we can see that the brain on the left here, which is a normal control, under these conditions is relatively inactive. The brain on the right is hyperactive.

This is an animal model demonstration of exactly what has been seen clinically, and I think it is of importance because it will now allow us to go on and look at interventions, to maybe be able to reverse this using this animal model as our test, so that we can then go on and see whether or not we can be effective in humans.

Now, as far as the issue of what we are doing in regard to the treatment of addicted babies, we have an extensive outreach program in terms of education. As you know, we have had information campaigns for a long time about the dangers of cocaine.

Several of those television advertisements and other media advertisements have specifically targeted mothers who are using this drug, pointing out to them very strongly and to their fathers that if they continue to do so that the neonate is in great danger of being born with brain damage.

Now, we are also attempting to educate primary care physicians who may see these mothers early in their pregnancy to recognize that these individuals are abusing drugs, specifically cocaine, and to counsel them and to work with them to get them into some type of drug treatment, so that they will cease and desist this drug use.

So we have a broad range of interventions designed to get these people to know that drug use during pregnancy is dangerous, specifically cocaine use is particularly dangerous; and second, to get primary care physicians to recognize patients who may be using drugs that do not admit it to them.

## DRUG ABUSE DATA

Senator CHILES. Doctor, it seems to me that we do not have very good information about the extent or the nature of drug abuse in this country. The survey of high school seniors misses dropouts, and the household survey is only conducted once every 3 years, so it misses the fast-changing patterns of drug abuse.

The emergency room survey of drug-related admissions and deaths is not very nationally representative. Would you agree with the assessment that we do not have adequate data on drug abuse in this country, and would you support the expansion of data collection efforts, such as those included in some of the reauthorization bills that are moving through Congress?

Dr. SCHUSTER. I share the frustration of the Congress and the public. When we quote 1985 statistics from our household survey, there is no question that we need to be able to have more accurate, timely information.

We are moving ahead in two areas to try and implement this: First, we are conducting a national household survey in this next year; and at the same time, we are going to be conducting telephone surveys, so that we can determine whether or not telephone surveys, which are cheaper and faster, will give us the same picture that our more expensive household survey gives. In other words, we will try to validate the telephone survey.

If we are able to do that, it would be possible for us to conduct telephone surveys on a much more regular basis and be able to keep the data up to date.

Second, as far as high school dropouts are concerned, this is a major concern. In the last household survey, we oversampled youth so that we could make some comparison between drug use patterns amongst those who were seniors in high school and those who had dropped out. And I can tell you that drug use is about 2½ times as great amongst the high school dropouts.

Senator CHILES. I am convinced it has to be. In fact, as I hear the 1987 statistics that you had in your statement, Mr. Trachtenberg, you are saying that cocaine is coming down.

I really want to believe those and I hope they are right, but what I see in my State in the use of crack and the prevalence and the gang wars and the territories and everything else, I see everything sort of telling me something else is happening.

Unless it is in dropouts, and there has got to be something wrong or my gut tells me something is wrong in the high school survey.

Dr. SCHUSTER. Well, let me point out that the high school seniors survey is a national survey, and when we say that cocaine use has gone down 20 percent, that is a national figure. It does not mean that in any specific community that that is going to be the percentage or that it has decreased.

We know in many communities it has increased, as is the case here in the Washington, DC, area. So these are national statistics and they are important for that regard, but they are not predictive of any particular State or community.

That is why we have formed what is called a community epidemiology work group, which involves a variety of State epidemiologists, so that we can get a handle on what is happening in local areas, not just national statistics which can be misleading about a particular community.

## ALZHEIMER'S DISEASE

Senator CHILES. Dr. Judd, your budget justification states that Alzheimer's disease affects an estimated 2 to 4 million Americans. I was surprised, because most of the estimates that I have seen I thought put it at 1.5 to 2 million.

Does that increase reflect higher incidence of the disease or is it improved diagnostic techniques?

Dr. JUDD. It may be related to an increasing sophistication in identifying the disorder and distinguishing it from other forms of dementia. The 1.5 million figure refers to those people with severe cases of Alzheimer's disease. The figure of 2 to 4 million people would include those persons who had been diagnosed as having mild, moderate, and severe Alzheimer's disease.

Senator CHILES. Your budget request would allocate about $18 million for research into all mental disorders of aging, not just Alzheimer's. This represents about a 4½-percent increase over the 1988 level, even though your Institute's research dollars would increase by about 7 percent.

Given the fact that we know that we are seeing this tremendous increase in aging population, which is where we have got to find the Alzheimer's, do you think your research plan really gives enough priority to the disease?

Dr. JUDD. Alzheimer's and mental disorders of the aging have a very high priority within the Institute. If you look back at the budget since fiscal year 1986, research on Alzheimer's disease has increased by nearly 50 percent.

Again, I would like to indicate that what you are seeing is only the increase in the mental disorders of aging budget category.

These figures do not reflect the full scope of the Institute's efforts in aging. For instance it does not cover the work in basic behavioral sciences, nor the basic neurosciences, where a significant portion of our aging research is being carried out.

## FETAL ALCOHOL SYNDROME

Senator CHILES. Dr. Gordis, as I understand it a recent Institute survey identified several characteristics that seemed to be associated with the risk of an alcohol abusing mother giving birth to a baby with a fetal alcohol syndrome. Can you please describe these risk factors and what they imply for prevention efforts?

Dr. GORDIS. Yes, Mr. Chairman. The fetal alcohol syndrome has been an important priority area for the Institute since the early seventies, and we have had an important group of investigators looking into the very kinds of questions you are asking.

It has been clearly established that the heaviest drinking mothers are the ones who are most likely to have a malformed offspring. The fetal alcohol syndrome is usually considered to have two components.

One is the grossly malformed infant with a variety of abnormalities of the face or the heart or joints and skeletal system, and the other component, which is seen in a larger proportion of the total number of infants affected by alcohol, is not so much these gross malformations of the body, but rather subtle but important intellectual defects, problems in development, right from the nursing period all the way up through the fourth year, a general low IQ throughout their life, and a persistence of whatever physical malformations they have had.

The estimate for the general population for fetal alcohol births is somewhere between 1 and 2 per 1,000 births nationally. However, when one considers the heaviest abusing mothers, that is the mothers who are drinking large amounts of alcohol, the estimate goes up by a factor of 20 to 30, to a level of 29 to 30 per 1,000 births among heavy drinking mothers.

Your question refers to what are the other features which lead to this, because clearly, even among the heaviest drinking mothers, not all go on to have an abnormal baby. So there must be other factors which, together with the alcohol itself, make certain infants especially vulnerable.

One of the factors, of course, is the dose and the pattern of the alcohol use itself, when it was taken, how much alcohol is being drunk, and how the same dose is spread out during the pregnancy.

Another has to do with race. It seems that black infants are susceptible to a larger degree to this, given a similar drinking history in the mother. There may be other factors, such as the genetics of the baby, malnutrition, social factors and so on, which we cannot get into in this discussion right now, which also play some role in distinguishing those infants who are especially likely to go that route with identical drinking histories in the mothers.

And there is some evidence, which I think still has to be confirmed, that various varieties of beverage alcohol do not all have the same potential, if drunk during pregnancy, of producing these abnormalities.

However, the issue is a very important one and it remains an important one. We have just funded a new center on that topic, Mr. Chairman. As far as the dissemination of the information which our research has produced, I am very happy to share with the committee a variety of publications, some aimed at the research community, but a far larger number aimed at the general population. These are available in various formulations in both English and Spanish and have been circulated extensively throughout the country.

Senator Chiles. Senator Bumpers.

### ALZHEIMER'S DISEASE ETIOLOGY

Senator Bumpers. I just have one question for Dr. Judd.

Dr. Judd, I wanted to ask you about different stories that appear from time to time dealing with Alzheimer's. And one is aluminum cookware.

Have you all been able to definitively establish that that is a contributor?

Dr. Judd. That was a hypothesis about 6 or 7 years ago. Research on this hypothesis was undertaken. The research found no link between aluminum cookware and Alzheimer's disease.

Senator Bumpers. So you have discarded that theory altogether?

Dr. Judd. Yes, sir.

Senator Bumpers. Is diet a factor?

Dr. JUDD. It is very difficult to know the etiology at this point of Alzheimer's disease. It could be a variety of things.

A number of areas are being investigated. Diet is not the major hypothesis that is being tested at this point.

The reason that aluminum looked like it might be a possibility is that aluminum deposits were found in the neurofibrillary angies of brains at autopsy. The feeling was that maybe the increase in Alzheimer's disease was related to increased use of aluminum cookware.

That was researched and proven to be incorrect. Really, the most current hypothesis is that there is a genetic locus on the human gene that codes for and regulates the appearance of Alzheimer's disease. We have been aware for a number of years that if senility or senile dementia, as it used to be called, occurs in one member of a family, that there was a significantly increased incidence in other members of the family.

We are, I believe, very, close and actually have begun to hone in on an area of the chromosome that we think will demonstrate a genetic linkage. And I think that what we are going to see is a report of gene linkage identification, and cloning of a gene for Alzheimer's.

That will open up a whole area of investigation into the molecular pathophysiology of the disorder that is not quite possible now. I believe that, with the increased focus on this disorder, we are beginning to nibble away at the edges, and I think we are beginning to come up with some very specific answers.

Senator BUMPERS. Well, that sounds encouraging. Thank you very much.

Thank you, Mr. Chairman. Mr. Chairman, I do have some questions I want to submit in writing.

Senator CHILES. Senator Domenici.

### CRACK COCAINE

Senator DOMENICI. Mr. Chairman, I would like to move to the drug problem and ask about crack. We are hearing a lot about crack. It is the newest major devil on the block. It has a lot of terrible qualities. Its usage is going up dramatically. It is cheaper than some of the other, more established drugs.

Congress is likely to put into place a huge new omnibus drug bill to address prevention, research, and demand and supply issues. And I wonder, with reference to crack, whether we know enough about how someone is addicted to crack and how we can help them?

Do we know enough about a course of treatment? We surely know something about heroin addiction and the other addictions. And we are spending a lot of money and hope to spend more getting drug users off the street and into facilities that can help them.

But what about crack?

Dr. SCHUSTER. I am very glad you asked this question, because we have doubled our budget in cocaine research over the past couple of years because of the recognition that this is the most frightening emerging problem in the drug abuse area.

Frightening because, frankly, we did not know how to treat those who were dependent upon cocaine. Let me say, when I rephrase your statement from crack to cocaine, it is because of course crack is one form of cocaine. We know that it is particularly insidious because it is the smoked form of cocaine.

Many people who would be unwilling to put a needle in their arm are willing to smoke a drug. But its rapidity of action is comparable, if not even faster, than when the drug is taken intravenously.

This is one of the characteristics that we know is associated with the dependence producing properties of a drug, that is rapid onset.

Second, because of the kinetics of this drug, it rapidly dissipates from the brain. It comes out of the brain very quickly. And so the person experiences a very peak feeling of euphoria within a matter of seconds, and then comes down from there.

Under those circumstances what usually occurs is that they take it again. By taking it again and again and again, they gradually exhaust the neurotransmitters in the brain which are responsible for the euphoria, and one of two things happen:

They run out of money, hopefully; or they continue to escalate the dose, in which case they can get into the range of dosages which have very, very toxic effects upon the heart. And this is of course one of the principal mechanisms of death associated with cocaine use.

We are in a period of rapid development in terms of knowledge about cocaine and how to treat it and its toxicity. But I would like to just point out one thing. When it comes to the development of the treatment of drugs, for the treatment of any form of drug abuse, there is not one pharmaceutical company in the world that devotes one penny for research for development in this area.

And this is because of the fact that it is simply not an economically lucrative area for private investors. As a consequence of this, new drug development for the treatment of addiction comes about in two ways:

Either because a drug which was developed for some other purpose is found to be useful for treatment of drug addiction; or the National Institute of Drug Abuse or some other group develops a new drug to the point where it then becomes financially lucrative for a private organization to take it over.

But I point this out because I think it is important that, unlike the other mental disorders, where there are pharmaceutical houses actively working with us, that is not the case in the area of drug addiction. So we have in the past couple of years really, I think, made some remarkable strides.

I would like to point out two things: first of all, in the area of treatment, there is a study that is going to be coming out from Yale University very soon which demonstrates that desipramine, which is a trycyclic antidepressant drug used currently for the treatment of depression, has been found to be extremely effective in curbing the craving that is associated with relapse to drug use following the time people have been detoxified from cocaine use.

What I am saying here is that when people come into a hospital setting, 7, 14, 21 days, and stop taking cocaine, it is easy for us to get them off of the cocaine. But over the next 6 months, they experience periods of intense craving, during which if there is any availability of the drug, if they can get it in any way, they frequently relapse to drug use.

Now, we have developed some behavioral procedures for dealing with that, adapted from relapse prevention with alcoholism and other forms of drug abuse. And they are effective for some people, but unfortunately not with many.

And so we needed something else. Dr. Kleber, looking at the basic research, judged that a drug such as desipramine would be effective in reversing some of the neurochemical deficits produced by cocaine exposure.

He tried it and has found that it is remarkably effective in preventing the craving and the relapse. Subsequently, when people are taken off the desipramine they remain drug-free for the period of a year, which they have now been studied.

And so we are very excited about this.

Senator DOMENICI. Any bad effects of the drug? Any side effects that are negative?

Dr. SCHUSTER. Desipramine is a drug that is relatively devoid of side effects. Let me hasten to say, however, that this would be useful only in people who are motivated to stop taking cocaine, unlike, for example, in the area of heroin addiction, where we have antagonist drugs which, whether you want to get high on heroin or not, if you have a drug like naltruxone in your body, you will not be able to get high on heroin.

We are looking right now to our basic research studies, at drugs that might be the counterpart of that, so that these drugs could be given to people who are not that highly motivated to stop using cocaine, but they still could not get high on the drug and therefore they would quit.

### WAR ON DRUGS

Senator DOMENICI. Mr. Chairman, you asked the question about statistics, the validity of the 1985 numbers, and the experts answered that they are trying to update them. I would just like to ask a follow-on question.

I know ADAMHA is not the whole war on drugs, the problem is very diffuse in our society, and we are trying to cure it with a lot of different approaches. Without laying blame or fault on any of the kinds of things that one might say, do you have an opinion as to whether we are gaining or losing ground in terms of the so-called war on drugs?

I mean from the standpoint of affecting our people. That is how you win that war. It is not how much cocaine we pick up. We are picking up more at the borders.

But do you have an observation for the subcommittee on whether we are winning the war on drugs in the sense of our goal of lessening drug use by our people?

Dr. SCHUSTER. Well, it is a mixed picture. The high school seniors survey I think is one of the most valid surveys about the population that it surveys, and that is those individuals who get to be seniors in high school.

We have to recognize, however, that about 15 to 20 percent of kids who enter school never get to be seniors, so we are not talking about them. Unfortunately, that 15 to 20 percent are concentrated in many of the major metropolitan areas in this country and therefore the dropout rate in some of the big cities is 40, 50 percent.

There the problem of drug use is abysmal. We do not really have a handle in terms of statistics on how bad it is, but every indication that we have indicates that it is not improving there.

On the other hand, if we look at our high school seniors survey, we see two things: first, a very significant change in the attitude of high school seniors about drug use. In the face of steady availability or increased availability, these kids are saying with an increasing frequency, drug use is dangerous, even experimenting with drugs is dangerous. That is, trying it once.

And the statistics show that from 1980 through 1988 or 1987, in all areas drug use amongst high school seniors has come down. For example, in 1980 almost 11 percent of high school seniors smoked marijuana on a daily basis. In 1987 it is 3.3 percent.

Now, that is still unacceptably high, but it is a significant decline. And that is not because there is less marijuana available.

And the same thing is true with cocaine. We have seen a 20-percent decrease in cocaine use at the same time its availability did not change.

And so I think it is an attitudinal change and followed by behavioral change which we are seeing in that population. But as I said before, we do have the high school dropouts, we have the kids in the large metropolitan areas where the drug use pattern is abysmal.

Senator DOMENICI. Thank you very much.

Thank you, Mr. Chairman.

Senator CHILES. Do we have any idea whether we have had those kinds of declines in that dropout population?

Dr. SCHUSTER. Declines in drug use?

Senator CHILES. Yes.

Dr. SCHUSTER. No, sir; I do not have data on that. We are attempting through our grant mechanism to look at cities within the United States with that kind of population. But we do not have enough information, historical information, like we have with the high school seniors survey and with the household survey to talk about trends.

## DEPRESSION AMONG THE ELDERLY

Senator CHILES. Dr. Judd, the National Center for Health Statistics has reported that three Florida metropolitan areas are among the 10 areas of the country with the highest suicide rate. Tampa-St. Petersburg has the highest suicide rate in the country.

Experts seem to think that Florida's high percentage of elderly residents is one of the reasons for these alarming rankings. I know the incidence of depression and suicide increases with age.

Update us, if you will, with your research on what the Institute is doing to identify effective treatments for depression among the elderly.

Dr. JUDD. We have made some very good inroads, Senator.

First of all, there has been a recognition of the different forms that depression takes in the elderly. One of the most common forms that it takes is a form of dementia which looks identical with any other kind of dementia. And yet, interestingly enough, it is the most common form of reversible dementia.

We have developed very good methods to identify and treat depression in the elderly. We are trying to get this information out to the practitioners in the country.

In addition, we have noted in the NIMH surveys that 19 percent of the successful suicides in this country each year are from individuals over 65 years of age. It is very clear that this represents an increased incidence of suicide in the elderly population.

And we are relating that rather specifically to the appearance of depressive disorders. We have developed new diagnostic techniques to identify depression in the elderly, biological profiles, techniques, and much more rational ways to treat it at this point.

Another thing that is about ready to emerge along this line is a prevention campaign that the Institute will be initiating on May 3—this is called the DART campaign, depression awareness, recognition, and treatment [DART].

This is the first prevention campaign the Institute has ever initiated. It is the first one in the history of the mental health field.

The reason we can launch such a campaign is the 20 years of very solid basic science research, that has essentially been funded and authorized by this committee. This 20 years of research has permitted us to understand what depression is, how to identify it reliably and validly, and how to effectively treat it.

We are at a point where clinicians can treat and manage 80 to 90 percent of depressed patients who come in to any health care giver's office.

We have gone from a rather vague understanding of a disorder that has existed in man for centuries to essentially a point where we can initiate a prevention campaign to educate and inform the American public and thereby identify the 10 to 15 million depressed individuals who are currently living in misery. Their suffering affects the way they are functioning in their jobs, the way they function with their spouses, and their parenting. They become part of the group, 1 in 14 of whom attempt suicide and are successful.

NIMH can initiate this campaign with the same degree of certainty that the National Heart, Lung, and Blood Institute did 15 years ago with its hypertension campaign. I think we will have the same excellent effect.

Senator CHILES. When are you going to start this campaign?

Dr. JUDD. On the 3d of May. And we would invite all of you to be present. We are kicking it off with a great deal of visibility because we know that the majority of individuals who are depressed in this country—and it is in the millions—are not being treated and not being identified.

Senator CHILES. How are we getting this information out? In other words, does the average doctor know that is treating some of these elderly patients or others, does he know what now is available or what could be done?

Dr. JUDD. We are in the process, Senator, of doing two things. We have a major program that has been put into place within the last year in which there will be one continuing medical education course a week given throughout this country to hundreds of physicians and mental health care workers, alerting them to the issues of depression, how to recognize it, and how to respond and manage it.

This may be a bit of a drop in the bucket at this point, but it is a beginning. The Institute is evaluating the success of this effort and if it is successful, we will be increasing it. There is, as you know, a lag in the acquisition of new information.

Senator CHILES. Absolutely. But my concern is that a place like Tampa-St. Petersburg, are we getting that information out to those physicians down there, where you are seeing the highest suicide rate?

Dr. JUDD. Absolutely. We are making that effort. But again the magnitude of the information dissemination effort is a difficult one.

We believe that the DART program will be a start and it will be expanded upon.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. Well, I have more questions, and I thank you for your patience of being here as long. Each of us probably have questions we would like to submit for the record.

We thank you very much.

Mr. TRACHTENBERG. Thank you very much.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### DRUG ABUSE TREATMENT

Question. Dr. Schuster, the problem of drug abuse is receiving increased attention these days, especially since IV drug abuse is linked to the transmission of AIDS. We hear different estimates of the number of addicts in this country and how much it would cost to treat them. I think it would be useful if you could set out, for the public record, the answers to the following questions:

-- How many serious drug abusers are there in this country, and what is their primary drug of abuse? How many of them use drugs intravenously?

Answer. According to the National Household Survey, which we last conducted in 1985, over 70 million Americans have used an illicit drug at least once in their lives. Nearly 23 million used an illicit drug in the month prior to the survey. Although we lack scientifically established estimates of the number of individuals who are currently using drugs to an extent that they require treatment, we believe that the number approaches 6.5 million, or 9 percent of those who have ever tried drugs.

In terms of drug of preference, about 900,000 of those in need of treatment could be considered primarily heroin abusers, 1.2 million are cocaine abusers, and the remaining 4.4 million users of a variety of other drugs.

We estimate that there are between 1.1 and 1.3 million intravenous drug abusers. This estimate includes both heroin and cocaine abusers who use the drug intravenously.

Question. How many of these addicts are currently or have been in treatment?

Answer. We estimate that there are currently approximately 250,000 drug abusers in treatment. Although we lack data that permit us to make an estimate, we would not be surprised if we found that the majority of long-term drug abusers have attempted treatment at one time or another.

Question. Setting aside for the moment the question of who pays, what would it cost to provide treatment to addicts not currently receiving it?

Answer. Based on our best current estimates, we believe it would cost, on average, about $19,400 to treat each drug abuser. This will pay for four cumulative years of enhanced treatment at $4,900 per year and should be sufficient to move a sizable portion of drug abusers into a drug-free life style. Current estimates for more traditional treatment is $3,900 per year.

From this estimate, one can consider several ways of estimating what it would cost to provide treatment for those in need. Assuming all treatment is provided at the enhanced level, one simple way is to multiply $19,400 by the number of people in need of treatment, 6.5 million, to get the estimate of $126.1 billion. A more practical approach, we believe, is to consider what portion of those in need the Nation should be able to treat at any one time and then make the estimate from that figure by multiplying it by the cost of a year of treatment, $4,900.

The recent recommendation of the President's AIDS Commission for expanding drug abuse treatment provides an example of how this approach works. The Commission recommended that 380,000 new treatment slots be established to treat intravenous drug abusers, allowing the existing 250,000 slots to be used to treat non-intravenous drug abusers. This would raise the total number of treatment slots to 630,000, which would be sufficient to provide treatment to approximately 10 percent of the 6.5 million people in need of treatment. Multiplying the enhanced treatment estimated average of $4,900 by 630,000 provides the estimate of $3.1 billion, which would include those funds currently being spent on drug abuse treatment.

Two important caveats in this estimate of treatment costs are that we currently know little about which treatment approaches are most effective for subpopulations of drug abusers and that the estimate yields only the cost of providing treatment. Any significant expansion of the nation's treatment capacity would involve an number of other activities. For example, new facilities would have to be provided, greater outreach efforts would have to be made, and more treatment staff would need to be trained.

Question. What share of treatment costs is picked up by the Federal government? States and localities? Third party payers?

Answer. We know very little about the amount spent within the private sector. If we limit our discussion to those programs that receive at least some public funds, however, we know that approximately 61 percent of the financial support for publicly funded substance abuse services comes from State and local governments, about 18 percent from the Federal government, and about 21 percent from private health insurance, donations, client fees, and other sources. For example, we estimated that in 1987 the Federal government spent approximately $538 million in drug abuse treatment: $293 million through various ADAMHA programs; $1 million through Social Security; and $244 million in Medicare and Medicaid. This does not include the Department of Defense, Veteran's Administration, and others.

Question. What percentage of untreated addicts would be dependent on public assistance to finance their care?

Answer. It is unlikely that private funds will ever play a dominant role in supporting drug abuse treatment. Because so many persons in need of treatment have either come from disadvantaged populations or have become economically disadvantaged as a result of their drug problem, most drug abusers do not have funds or insurance coverage for treatment. Of the drug abusers who enter clinics supported by public funds, 66 percent are unemployed and 62 percent have no form of health insurance. Publicly funded treatment is not necessarily "free" treatment. Programs that once relied exclusively on government support and donations from the private sector have found it financially necessary to begin charging clients for a portion of their services.

Question. If more funding were provided for treatment, how much of an increase in caseload could the treatment system absorb in the next year?

Answer. Treatment program administrators tell us that, if additional funds were available, they should be able to expand capacity by 20 percent in the next year. Beyond that, a major national effort would have to be mounted to recruit and train staff, establish new treatment facilities, and garner community support for treatment expansion. It should be noted that, the treatment system should already be expanding because of the emergency infusion of Federal treatment funds appropriated through the Anti-Drug Abuse Act of 1986 and the increases provided in the FY 1989 President's Budget.

## BLOCK GRANTS

Question. What information do you have about how states are allocating their block grant funding between alcohol and drug abuse programs?

Answer. The Alcohol, Drug Abuse, and Mental Health Administration is currently receiving and reviewing the Alcohol/Drug Treatment and Rehabilitation (ADTR) Block Grant Annual Reports submitted by the States and will have a better understanding of how the funds were allocated between alcohol and drug abuse in the near future. Until then the only information we have comes from the applications submitted by the States.

The information contained in the applications is in the form of anticipated utilization and estimates of accomplishments. Analysis of the applications indicate that the States "estimate of the clients to be served..." in FY 1988 exceeds 290,000. Approximately 65 percent of the clients are alcohol abusers and 35 percent drug abusers.

States were not asked, as part of their application, to separate out the amounts of ADTR funds allocated between alcohol and drug abusers. Any attempt to project a funds distribution between alcohol and drugs based on a "clients served" basis should keep in mind that traditionally the cost of drug treatment is significantly higher then for alcohol. Per client treatment cost are as much as three times higher for drug clients.

Preliminary analysis of the data provided by the States to the National Association of State Alcohol and Drug Abuse Program Directors (NASADAD) in response to their State Alcohol and Drug Abuse Profile (SADAP) survey indicates that the States able to separate their drug abuse from their alcohol programs indicates that the ADTR Block Grant funds will be utilized at a rate of more then two to one for drug abuse. When the final SADAP report is complete a more detailed analysis may be made.

Question. Are States recognizing the severity of the drug problem by targeting block grant money to drug abuse?

Answer. The Anti-Drug Abuse Act directed that the ADTR Block Grant "may be used by the State for alcohol abuse and drug abuse" treatment and rehabilitation programs and activities. These funds were largely to provide activities to increase the availability and outreach of programs and to expand the capacity to provide such services to reach the greatest number of people in need, according to the priorities that exist in the individual State.

Recently compiled information from State ADTR applications does indicate that, nationally, States will treat twice as many alcohol abusers as drug abusers. It is important to note, however, that this 2-to-1 client ratio does not necessarily equate to how the dollars will be spent. It is more likely that the dollar split for all States will approximate the 50/50 split previously noted by NASADAD for publicly-funded treatment programs.

A number of States with high-priority drug problems, such as New York, have chosen to expand a major share of their ADTR monies on drug abuse problems. A preliminary analysis of the data provided by States to NASADAD in response to the SADAP survey indicates that for those States able to separate their drug abuse from their alcohol programs utilize ADTR Block Grant funds at a rate of more then two to one for drug abuse. When the final SADAP report is complete a more detailed analysis may be made.

## DRUG TREATMENT DROPOUTS

Question. Dr Schuster, much attention has been focused on the importance of treatment programs as a way to attack the demand side of the drug problem and also to stop the transmission of AIDS. Yet, we hear that there are very high dropout rates in treatment - as high as 60 to 80 percent in some programs. If the average client leaves a treatment program before he is really ready to live drug-free, I wonder whether it makes sense to put a lot more people into treatment.

Can you please tell us what the dropout rates are for the various types of treatment programs and comment on the utility of increasing the number of treatment slots before we find out what works to keep a client in treatment.

Answer. Keeping clients in treatment has been a central concern and a topic of considerable study in evaluating treatment effectiveness. The drug abusing population is difficult to treat, and dropout rates are higher than we would hope for. However, dropout rates are not the most important factor in treatment outcomes. Simpson (1980) looked at factors in treatment retention for a sample of nearly 1,500 intravenous opiod drug users in four different types of treatment and found that the amount of time spent in treatment was far more important than completion of treatment.

Those entering treatment will typically have multiple treatment episodes, and most will either stop or sharply curtail their use of drugs after one or several treatments. In Simpson's landmark study, by the fifth year after entering treatment, over 60 percent of the drug abusers had maintained abstinence from opioids for at least a year. Moreover, only 21 percent continued to use opiods daily over the long term. Many of those who quit using opioids left treatment early, only to go back into treatment. Thus, a static view of dropout rates alone does not give the whole picture.

Different treatments have different retention rates. Drug-free residential treatment programs, such as therapeutic communities (TC) have the highest dropout rates of any modality. Drug users typically find the early weeks of treatment to be difficult, and the TC's challenging, confrontational paradigm is especially stressful. About 44 percent leave in the first 4 weeks, and an additional 16 percent leave within the next 4 weeks. This treatment modality accounts for about 8 percent of our treatment capacity. It retains in treatment only those who are strongly committed to change. Clients who successfully complete such programs, however, tend to have favorable outcomes.

However, clients who leave drug-free residential often find their way into outpatient programs that involve less interpersonal stress. Drug-free outpatient is the largest treatment modality, about 46 percent of total capacity, and loses only about 22 percent of clients in the first 4 weeks with an additional 16 percent in the subsequent month.

Methadone maintenance accounts for 40 percent of treatment capacity and provides longer term treatment. Maintenance programs, because they offer an acceptable alternative to heroin and give respite to the drug user from the painful lifestyle common to unregulated addiction, have a higher client retention rate than other modalities. Methadone maintenance treatment has an attrition rate of only 13 percent in the first four weeks with an additional 10 percent in the second four weeks. Thus, 77 percent of methadone maintenance clients stay in treatment nine weeks or more.

There are many influences that impinge on a client's readiness to live drug-free. To help drug users to live drug-free is certainly the most desirable treatment outcome, but it is often not the most realistic. Individuals enter drug treatment for a variety of reasons. Often treatment is sought because of a drug-related crisis. Once the immediate problem has been managed, some clients may leave treatment. The next crisis may prompt a return to treatment. And it may take several episodes of crisis and treatment before the drug user is convinced of the need to alter his or her lifestyle by becoming abstinent. Therefore, readiness for treatment involves many things -- some degree of experience and maturation, pressures from the immediate environment including law enforcement, employers, or family, and interest on the part of the drug abuser in getting away from the drug abusing lifestyle with its attendant risks. While some addicts may even give up drugs without treatment, these are not typical, and most need help. Expansion of treatment capability would permit a greater number of first time clients at any given time as well as providing greater availability for repeat clients.

One approach to reducing the unacceptably high dropout rate is to make treatment more responsive to needs. For example, a more flexible methadone dosage policy has been shown to increase retention. Likewise, use of a narcotic antagonist, naltrexone, has led to higher retention rates in some counseling programs. It is also likely that a combination of pharmacological treatment and continued legal supervision of those forced into treatment by the criminal justice system would aid in retention.

Retention in TC programs is a problem receiving attention by researchers. At Phoenix House in New York City, retention was improved when special counseling sessions, some of them involving family members, were held during induction into the program. It is also worth noting that these programs are becoming more diversified by offering outpatient components.

Another area with potential is the treatment of co-morbid conditions, such as depression or anxiety disorders, that are common among intravenous drug abusers. A recent study found short-term psychotherapy to be of value in improving outcomes for psychiatrically troubled methadone patients. Other studies have also found specific pharmacological treatments (such as lithium and antidepressants) to be useful in treating addicts with co-morbid conditions. These tend to improve outcomes generally and should enhance retention, although it is too early to tell the magnitude of this enhancement.

## EFFECTIVE DRUG ABUSE PREVENTION

Question. Dr. Schuster, it seems as if drug abuse prevention research has not been a high priority for the Institute in the past, although I'm glad to see that it is now one of the larger line items in your extramural research budget. My impression is that we haven't learned much from existing prevention research, either because the quality of the evaluations has been poor or because the programs evaluated have not been effective.

-- How much can we say we know about drug abuse prevention? What programs have been shown to be effective?

Answer. The prevention research program at The National Institute on Drug Abuse includes both etiologic research designed to identify relevant biologic, behavioral, and social precursors to drug use and abuse, and intervention research designed to test under controlled conditions the efficacy of theory-based preventive interventions.

NIDA's investment in both areas of prevention research has been considerable over the last 15 years and has provided valuable data on the causes of drug abuse and has identified promising preventive interventions. In fact, although our scientific knowledge in prevention is far from complete, we have learned a great deal from our prevention research efforts.

In our view, the key to the development of effective prevention programs is the creation of scientifically sound knowledge through quality research. Over the last 15 years NIDA sponsored research has generated invaluable scientific data concerning the abuse liability of a variety of substances, including marijuana and cocaine. The key objective for drug education programs is to improve drug knowledge and to develop an accurate perception of the harm associated with drug use and abuse. To meet this objective, NIDA's research findings of the psychological and physical risks of drug abuse have been incorporated into most school-based drug curricula.

The National High School Senior Survey is a valuable source of trend data on the main prevention target population. The last two surveys have indicated a downward trend in self-reported marijuana and cocaine use. In addition, an increased perception of harm was associated with drug use. While our scientific knowledge of the efficacy of specific prevention programs is still evolving, these declines in marijuana and cocaine use with an increase in perceived risk of harm, provide encouraging initial indications that the drug prevention message is effectively reaching a large proportion of our adolescent population.

Though progress has been made, more advanced basic research is needed to identify the abuse potential of the ever increasing array of abusable drugs and to expand scientific knowledge of the neurochemistry of behavior, emotions, motivation, and mood states. NIDA intends to expand its applied research program to assess the efficacy of theory-based preventive interventions appropriate for implementation in schools, communities, and work-sites across the country. Special attention also will be given to the special needs of individuals who are more vulnerable to drug abuse because of psychological, social, and environmental risk factors. Finally, while we are encouraged by the decline in drug use by High School seniors, we are well aware that drug use by school dropouts remains a serious problem. NIDA will also expand it efforts to find effective prevention programs directed at this group.

NIDA and the Office of Juvenile Justice and Delinquency Prevention (OJJDP) are working jointly on a program to develop research on the etiology of drug abuse among ethnic and minority juvenile populations. Despite major strides in etiologic research and preventive intervention research, largely with school-based populations comprised predominantly of white, middle class youth, only limited information has become available on drug abuse among youth in ethnic minority populations. The purpose of the NIDA-OJJDP program is to expand research in this area. The program is currently focused on three areas. 1) Identifying factors that may place minority individuals or groups at above average risk for AIDS. The higher prevalence rates for AIDS among minority populations merits special attention. The early age of onset for sexual activity, drug use, and intravenous drug use by some minority youth and their beliefs and practices regarding health maintenance and the future may make them unable to relate to public health messages on AIDS which are addressed to other populations. 2) Identifying the interactional effects of minority status, acculturation, drug abuse, and juvenile delinquency and criminal behavior. 3) Identifying minority subgroups and individuals at high risk for drug dependency in conjunction with developing and evaluating interventions to prevent initiation and escalation of drug abuse.

NIDA's basic and applied research programs have contributed to the development of promising prevention strategies that include information dissemination, social skills development (specifically in the area of peer resistance training), the identification of high-risk youth, and early intervention programs. In the clinical intervention area NIDA is supporting a number of research studies that are evaluating the effectiveness of strategies for preventing the onset and progression of drug abuse.

Most published prevention research studies have focused on the prevention of cigarette smoking and have tested these interventions with sixth, seventh, or eighth grade predominately white students. Recent reviews of this research suggest that smoking prevention programs that attempt to provide youth with social skills to resist the societal pressure exerted by peers, families, and the media to smoke can significantly delay onset of new smoking. NIDA is currently supporting research to determine whether prevention programs based on social learning theory would have generalized effects for the prevention of not only cigarette smoking, but also the initiation of alcohol, marijuana, cocaine, and other drugs, and to determine how long the effects of these programs last.

## NATIONAL SCHIZOPHRENIA PLAN

Question. Your budget requests $ 40.2 million for schizophrenia research. That's almost a 10 percent increase over the 1988 level and about double the increase requested into other mental disorders.

Does your budget request reflect full first-year implementation costs for the national schizophrenia plan? If not, what additional funding could be responsibly spent in 1989 to carry out the first year of the plan?

Answer. The NIMH is increasing research on schizophrenia and basic brain and behavior approximately 10 percent, while holding areas like child mental health, aging and Alzheimer's disease, and depression to a 5 percent inflationary increase. While we believe these are priority areas, it is the Institute's goal to concentrate as much attention and resources as possible on the National Plan for Schizophrenia Research and our neuroscience plan "Decade of the Brain".

The budget request does not reflect the full first year implementation costs of the National Plan for Schizophrenia Research. Full funding would require an additional $54.8 million. These funds would be used to initiate new project grants, research centers, research scientist development awards, research training, and equipment grants. Substantively the areas the Institute would focus on are: heterogeneity of schizophrenia, neuroscience workgroups on brain and behavior, medication and treatment of the positive and negative symptoms of schizophrenia, genetic markers for schizophrenia, neurological bases for schizophrenia and other serious mental illnesses.

## ALCOHOL ABUSE AMONG WOMEN

Question. Dr. Gordis, your budget justification states that there isn't evidence to support the common belief that the percentage of women who drink heavily has been increasing. But I was under the impression that alcoholism is more of a "hidden disease" among women - that female alcohol abusers are often missed in surveys and may be very reluctant to seek treatment. I also understand that women are more sensitive to alcohol, become addicted more easily and develop alcohol-related physical problems more quickly.

Please tell us what is currently known about the incidence of alcohol abuse among women and the special characteristics of this addiction among females.

Answer. Household population surveys of alcohol use, dating back to 1967, do not indicate a convergence in the drinking patterns of men and women. These surveys consistently indicate that men consume more alcohol than women at all ages.

Per capita consumption of absolute alcohol has increased from 2.3 gallons in 1967 to nearly 2.8 gallons in 1983. This trend has been accompanied by modest increases in consumption in the general population, especially among younger men.

Between 1967 and 1983 the prevalence of current problems related to alcohol increased significantly in young males, and also increased in younger females, although the increase in females was not statistically significant.

While the prevalence of heavier drinking is lower among women then men, heavier drinking women report relatively higher levels of problems then do men reporting the same levels of drinking. Women also report higher levels of intoxication than men when consuming the same amounts of alcohol. There is also evidence that chronic alcohol use has a greater physiological impact upon women than upon men.

While household surveys are known to under-estimate the amount of alcohol consumption, when compared to sales data, there is no evidence to suggest that female alcohol abusers are missed in surveys more than their male counterparts.

## HOMELESS CHILDREN

Question. Dr. Judd, we read heartbreaking stories in the press about the increasing numbers of children who are homeless. They face stresses and tensions that children shouldn't be expected to bear. You allocated $1,000,000 in 1987 homeless mentally ill demonstration grant funds for projects focusing on homeless children and adolescents. And you're requesting $2.2 million in 1989 for Community Support Program grants for homeless children with emotional problems.

-- Tell us how communities can use these funds to help homeless children overcome the emotional problems that seem to be almost an inescapable part of their situation.

-- Can the amount of funding you're requesting really make a dent in the problem?

Answer. There are two major ways in which our demonstration grants can be utilized to assist in meeting the needs of homeless children and adolescents and those who are at high risk of becoming homeless. First, under our Child and Adolescent Service Systems Program, the major goal is to increase the availability of continuums of care for emotionally disturbed children and adolescents at the community level and thus improve the availability and access to appropriate services for children and their families. Making a wide range of services available and accessible to families will in many cases help prevent homelessness. In addition, for those children and adolescents who are already homeless, our demonstration grant funds can be utilized to identify vulnerable children in shelters and on the streets, provide an assessment of their mental health, drug, and alcohol abuse treatment, health, parenting, education, and housing meeds, and provide appropriate referral of these homeless children and their families to appropriate community resources. For those homeless children and adolescents who are identified as severely emotionally disturbed or at high risk of becoming severely emotionally disturbed, the demonstration grantees can develop and test out special outreach, case management, and treatment approaches. It should be kept in mind that these demonstration funds are to develop, demonstrate, and evaluate new approaches. They can help communities understand what works and what does not work with this population. The resources to meet the total needs of homeless children and adolescents will have to come from other sources.

### DRUG TREATMENT TRAINING

Question. Dr. Schuster, when the need for expanded drug treatment programs is discussed, we also hear about the need for more drug abuse counselors. I know that the National Institute on Drug Abuse proposes to spend around $6 million training drug abuse counselors about AIDS, but I'm not aware of any other training that the Institute provides.

Do you think that private sector training programs will respond adequately to the demand for drug abuse workers if treatment programs are expanded? Are there currently shortages in the drug abuse counselor field or are programs adequately staffed? What role do you envision for your Institute in addressing any current or future staff shortages?

Answer. NIDA has met with the National Association of State and Alcohol and Drug Abuse Directors where the consensus was obtained that there is a critical shortage of trained professional and paraprofessional drug abuse treatment personnel. In addition due to stressful work environments and often times low salaries, retention of trained personnel may be difficult. The staffing shortage seems particularity acute in areas of high treatment demand.

Currently, there are few programs in the private sector designed specifically for the training needs of drug abuse counselors. Since both professional and paraprofessional drug abuse counselors are essential to ensure effective treatment, training needs must be addressed on several levels. Short-term training needs of new and existing drug abuse treatment personnel must be addressed through the development and implementation of inservice and other continuing training programs. This training should be directed primarily towards paraprofessional counselors. Long-term needs for qualified drug abuse treatment professionals must also be addressed. Only a relatively small number of university-based programs provide adequate training for the health professions in the treatment of drug abuse. As a result, most health professionals (e.g., physicians, nurses, psychologists, and social workers) who enter the field are ill-prepared to deal with substance abuse clients. A health professions training program is needed to encourage the development of relevant curricula within professional schools to provide fellowships/traineeships to encourage students to enter the drug abuse field. States can address such needs through the use of block grant funds.

Staff shortages may be addressed as follows. Currently NIDA estimates that there are 81.4 direct-care drug abuse staff for every 1,000 patients--or 12,047 staff for the 148,000 intravenous drug abusers believed to be in treatment. We estimate that at least 50 percent (6,024) of existing staff need training to upgrade their basic drug abuse treatment skills and that 75% (9,035) need AIDS-related training. In order to improve the quality of treatment the staff/client ratio will mean that currently existing programs will have to recruit and train an additional 2,679 individuals. In 1989, 2,846 individuals must be recruited and trained for new programs that will be developed. Initial training should take place over the first two years of a staff members employment; with a basic drug abuse course and an AIDS course in the first year, and an advanced drug abuse course in the second year. After the initial training, 25 percent of all staff should receive drug abuse and AIDS refresher training in each of the remaining nine years of the plan.

## DRUG ABUSE PREVENTION INFORMATION DISSEMINATION

Question. Dr. Schuster, we hear occasional concerns about how schools and communities are spending their drug abuse prevention grants from the Department of Education -- whether they have the information necessary to develop successful programs.

I know the Office of Substance Abuse Prevention and your Institute are conducting demonstrations and research to identify effective drug abuse prevention strategies for school children. But I'm wondering whether that information is getting into the hands of people at the local level who are trying to operate prevention programs. Please tell us how you disseminate your information about prevention to communities and schools, and how you coordinate your efforts with the Department of Education.

Answer. The Office of Substance Abuse Prevention (OSAP) reaches communities and schools through its National Clearinghouse for Alcohol and Drug Information (NCADI). The Clearinghouse disseminates information directly and indirectly through intermediary organizations that have channels already established to reach these audiences.

A recent promotion undertaken by the Clearinghouse is a good example of how the Clearinghouse directly disseminates information to local communities. The National Association for Children of Alcoholics prepared an educational packet for elementary school administrators on the unique problems and risks for children of alcohol abusing parents. NCADI mailed the packet, along with an OSAP flyer to every elementary school in the country, using mailing labels supplied by the Department of Education. The OSAP flyer contained in the packet informed recipients about the opportunity to order the booklet "What Works: Schools Without Drugs" from the Clearinghouse. Over 6,000 requests for this booklet were generated from this announcement and filled by NCADI.

OSAP is intensely involved in the development of a new publication series specifically intended for community members interested in alcohol and other drug abuse prevention. The series is known as the "Drug-free Communities" series, and contains an informational booklet along with a more detailed, hands-on, technical assistance manual. The series containing "state-of-the-art" information on prevention will be available in the Fall or Winter of this year and will be widely disseminated through the Regional Alcohol and Drug Awareness Resource (RADAR) network.

NCADI makes extensive use of intermediary organizations to get information out to the public. NCADI is currently working with the General Federation of Women's Clubs, the largest services organization of volunteer women in the world, to disseminate prevention materials targeted to parents and children. NCADI works with many other groups, including the National Council on Alcoholism (NCA), to inform the public about the risks of fetal alcohol syndrome (FAS) and the National Crime Prevention Council on projects of joint interest, such as the development of comic books for children or materials useful to law enforcement professionals.

NCADI recently coordinated the assembly of an FAS Awareness Week packet for NCA.

The National Clearinghouse for Alcohol and Drug Information (NCADI) provides prevention information and dissemination services for the National Institute on Drug Abuse (NIDA), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the Office for Substance Abuse Prevention (OSAP), Department of Education, and other Federal agencies involved in Alcohol and drug information efforts. Specific collaborative activities with the Department of Education that have been coordinated through NCADI include:

> Distribution of Department of Education materials such as Schools Without Drugs, the Challenge newsletter, and posters to schools, youth-serving organizations, voluntary associations, and community groups;
>
> Development articles for the Challenge newsletter;
>
> Provision of prevention information resources in response to requests from groups that have received Department of Education funding under the Drug Free Schools and Communities Act;
>
> Implementation of the RADAR Network which consists of 100 State clearinghouses and prevention resource centers, the information centers of national voluntary organizations, and the five Department of Education Regional Training Centers.

The RADAR Network provides its members with comprehensive communication support services such as OSAP's regional communication seminars which provide training on strategies for research on high-risk youth; technical assistance in areas such as message testing, materials development, and media campaign implementation; and priority access for ordering new alcohol and other drug publications. Because the Department of Education's Regional Training Centers work closely with schools and communities, NCADI works to ensure that they are kept abreast of state-of-the-art prevention research findings through Prevention Pipeline: An Alcohol and Drug Awareness Service and listings of prevention materials for elementary and secondary students, parents, and teachers.

NCDAI also works together with various Department of Education offices in the development of resources for college students, administrators, and faculty. The Office for Educational Research and Improvement (OERI) and the Fund for the Improvement of Postsecondary Education (FIPSE) are both involved in a NCADI working group that is developing new college resources. NCADI has provided conference support to FIPSE and has assisted OERI in planning efforts for the "Network of Colleges and Universities Committed to the Elimination of Drug and Alcohol Abuse."

The National Drug Abuse Policy Board offers other opportunities for Department of Education and OSAP to collaborate. OSAP staff serves with the Department of Education on the Education and Prevention Committee and chairs the Subcommittee on the Clearinghouse.

With respect to disseminating the findings from the OSAP demonstration grants, it should be remembered that these grants were awarded in September 1987 and are currently in their first year. Most of them have awards for two or three years. Thus, it is premature to have any findings to report at this point. However, OSAP is developing dissemination plans for this grant program. A set of guidelines is being developed which will result in Implementation Manuals as the final report from each grantee. These manuals will provide the critical details required for replication of the projects. OSAP expects to distribute these manuals through the Clearinghouse as well as through other channels.

OSAP also plans to sponsor national and regional symposia and conferences during the next few years where widespread dissemination of grant findings will be featured and where the availability of products such as manuals, videos, curricula, and assessment instruments, developed under the grant, will be announced and made available to the field. Finally, OSAP is developing a learning community which will include, in addition to the OSAP grantees, national organizations, State and county governments, and researchers. Its function is to facilitate and stimulate information sharing and to serve as a medium for the dissemination of findings emerging from the demonstration grants.

## PCP TREATMENT

Question. Dr. Schuster, Here in Washington we hear a lot about the frightening consequences of using the drug PCP. Some of the most horrifying and violent crimes in the area have been committed by people under the influence of PCP. I know that PCP is also a serious problem in other major metropolitan areas like Chicago and Los Angeles. Worst of all, I understand that currently there is no effective treatment for PCP users.

Is this true? Can you tell us what research your Institute is doing to identify effective treatments for PCP abuse?

Answer. PCP is indeed a major problem. Approximately 45 percent of PCP emergency room cases are results of combining PCP and alcohol, PCP and cocaine, and PCP and marijuana. Fortunately, PCP has gained a ~~bad~~ "bad" street reputation due to its unpredictable side effects, which has probably discouraged widespread use and experimentation. There is currently, however, a localized pattern of use in certain urban areas including Washington, D.C., Los Angeles, and New Orleans.

Since PCP is a habituating drug, rather than physically addicting, treatment takes on several meanings. The immediate need is often to detoxify the individual in acute duress. As with most drugs, however, there is no specific antagonist for reversing effects from PCP. Therefore, conventional therapies, such as urine acidification and forced diuresis, are the only available treatments. Amelioration of symptoms with supportive therapies is currently the primary treatment. After the initial crisis is past, drug abuse therapy may be offered.

There is however, some promising research underway. The PCP binding receptors are under intense investigation and are leading the way to the development of compounds that are antagonists or inverse agonists of binding and related functions at PCP and sigma sites. Another promising approach is immunologic in character. Antibodies specific for PCP are used to bind up and eventually clear from the body, free PCP. Much more basic research is needed to amplify understanding of the mechanism of action of PCP.

## TREATMENT OUTCOME RESEARCH

Question. Dr. Gordis, I'm interested in the new treatment outcome research projects you've initiated with $2.3 million in Anti-Drug Abuse Act funding. I understand you've awarded five grants in 1988 to test the effectiveness of inpatient versus outpatient programs for abusers with different types of drug dependence.

Tell us how this outcome research is different from previous drug treatment research and demonstrations. I've heard it compared to a "clinical trial".

Answer. The $2.3 million in Anti-Drug Abuse Act funding is being jointly administered by NIAAA and NIDA. The two Institutes are funding five research studies that investigate the appropriateness of residential or inpatient treatment as opposed to outpatient treatment for individuals with alcohol dependence alone, cocaine dependence alone, or both dependencies.

These studies are not clinical trials of new treatment approaches. Rather, they are comparing commonly used inpatient or outpatient treatment regimens. The new program builds on previous treatment efficacy studies supported by the regular research grant program which tended to be smaller in scale and were primarily concerned with the development of research methodology for treatment assessment, and thus of a preliminary nature to the current initiative.

A key characteristic of the studies being funded under this initiative is that they study treatment outcomes when the type and severity of substance dependency have been carefully matched to what is considered to be an appropriate treatment regimen and setting. Another key characteristic of these studies is that patients are either randomly assigned to treatment groups or are matched to one another on the basis of characteristics that might be expected to affect treatment outcome, such as severity of addiction and psychiatric status.

Question. Rather than focusing on particular drugs that are abused, some say that it is more important to select treatment for an addict based on his characteristics -- evidence of mental disorder, family and job status, etc. -- regardless of the drug he is abusing.

How do you plan to test this hypothesis with the four new outcome research projects you propose to fund in 1989?

Answer. There are common features to all addictions, for example, compulsive drug-seeking behavior, drug "hunger" or "craving", which are no doubt important. On the other hand, drugs differ markedly among each other in their effects on the brain. For example, alcohol and cocaine have different effects on nerve cell membranes, neurotransmitters and electrophysiology. As we continue our efforts to improve treatment, one target of research will be to determine whether the common elements in addictions or the neurophysiological differences are more relevant to treatment.

## RESEARCH PROJECT GRANTS

Question. How many more research project grants could be funded within the President's 1989 request if you assume and average cost of 95 percent rather than 100 percent of the council-approved rate?

Answer. ADAMHA has given much thought to the relative value of funding more grants by reducing the amounts approved by the council review process. The FY 1989 President's Budget clearly reflects the determination to ratify the judgement of the scientific and advisory bodies incorporated into the council-approved funding levels. While it is possible to provide a specific answer to the question, the response must be evaluated in light of our best professional opinion that to reduce grant levels to support additional grants would not be in the best interests of scientific progress.

Given the preceding discussion, approximately 88 additional research grants could be funded by assuming an average cost of 95 percent. Of the total, 45 are additional competing renewal awards while 43 are additional new grants. The estimate would provide 52 additional awards to NIMH and 18 additional grants each to NIDA and NIAAA.

Question. Why has the average cost of a NIDA research project grant risen 33 percent from 1987 to 1989, while the average cost of NIMH and NIAAA grants has increased by only 12 and 17 percent respectively?

Answer. There are several reasons for the increase in NIDA's average grant costs. The table below may help clarify the issue.

| | FY 1987 | | | FY 1989 | | | |
|---|---|---|---|---|---|---|---|
| | No. | Amount | Average | No. | Amount | Average | Inc. |
| Conts | 236 | 38,786,000 | 164,347 | 281 | 50,299,000 | 179,000 | 8.92% |
| Comp | 65 | 11,847,000 | 182,262 | 54 | 12,280,000 | 227,407 | 24.77% |
| New | 136 | 18,367,000 | 135,051 | 36 | 5,891,000 | 163,639 | 21.17% |
| | 201 | 30,214,000 | 150,318 | 90 | 18,171,000 | 201,900 | 34.31% |
| Sup. | 27 | 708,000 | 26,222 | 8 | 221,000 | 27,625 | 5.35% |
| Total | 437 | 69,708,000 | 159,515 | 371 | 68,691,000 | 185,151 | 16.07% |

One of the major reasons for the increase in average costs of new and competing grants is the change in the mix of new and competing grants. As can be seen from the table above, the increase in competing renewals and new grants individually is around 22 percent, but when they are combined, the increase is 34 percent. Thus, about a third of the increase is not due to an actual increase in the cost of the grants funded, but a change in the mix of new and competing grants.

In 1987, with the large infusion of funds from the drug initiative, NIDA funded twice as many new grants as competing renewals. In 1989, NIDA will fund more competing renewals than new grants. This is a reflection of the priority we place on honoring our commitments to established researchers in the drug abuse field. Because the average cost of competing renewals is higher than the average cost of new grants, this will drive the overall average up higher.

Another reason for the increase is that it reflects the emphasis the Institute has placed on applied clinical studies. Clinical studies of such topics as the most effective way to treat adolescent cocaine users or how to care for addicted babies are generally much more expensive that animal studies or basic research. In addition to paying for the research itself, we must also pay for the associated costs of treatment and patient care staff. Grants in this area often cost two or three times what a basic laboratory study might cost. Thus one of the consequences of NIDA placing more emphasis on treatment research has been the increase in average grant costs you see in the budget.

## ALZHEIMER'S DISEASE

Question. Please provide for the record a chart displaying total ADAMHA and National Institutes of Health resources devoted to Alzheimer's Disease research from 1987 through 1989.

Answer. The following chart reflects funding levels in support of Alzheimer's disease direct research.

Alzheimer's Disease and Dementias of Aging
(Dollars in thousands)

| | 1987 Actual | 1988 Estimate | 1989 Estimate |
|---|---|---|---|
| National Institute of Aging | 42,038 | 54,956 | 58,667 |
| National Institute of Neurological and Communicative Disorders and Stroke | 18,611 | 19,900 | 21,830 |
| National Institute of Allergy and Infectious Diseases | 1,446 | 1,493 | 1,569 |
| National Eye Institute | 62 | 63 | 0 |
| Division of Research Resources | 2,010 | 2,183 | 2,004 |
| National Center for Nursing Research | 269 | 260 | 280 |
| Total, NIH | 64,396 | 78,855 | 84,350 |
| Alcohol, Drug Abuse and Mental Health Administration | 10,012 | 10,965 | 10,702 |
| TOTAL, ALZHEIMER'S DISEASE | 74,408 | 89,820 | 95,052 |

The National Institute of Mental Health funds a broad spectrum of basic research, public education efforts and service demonstration programs with relevance to mental disorders of the elderly in general and Alzheimer's disease in particular, which are not reflected in the figures above.

## OFFICE OF FINANCING AND COVERAGE POLICY

Question. Please provide a listing of the activities of the Office of Financing and Coverage Policy.

Answer. ADAMHA's Office of Financing and Coverage Policy, established in the Office of the Administrator in June 1987, developed and implemented a range of crosscutting Alcohol, Drug Abuse, and Mental Health services and services financing research studies; initiated a process for enhancing the agency's data development and management capabilities; and administered the Alcohol, Drug Abuse, and Mental Health Services Block Grant and a special Substance Abuse Block Grant.

The OFCP research and evaluation agenda encompassed an update of a 1983 ADM economic costs to society study; the evaluation of the impact of alcohol abuse services delivered in settings not currently covered by Medicare and Medicaid; a study to re-abstract psychiatric inpatient hospital medical records data in order to assess the current structure and pricing levels employed under Medicare's DRG prospective payment system; development of an "evaluability study" to assess the feasibility of updating the agency's knowledge of the organization, structure, financing and referral pattern related to ADM services in the public and private delivery system; a contract with the Institute of Medicine to study the financing and coverage of substance abuse services with a focus on the extent and adequacy of coverage for substance abuse care; and completion of a study resulting in restructuring of the DRGs for HCFA's prospective payment system for alcohol and drug services in Major Diagnostic Category 20 (MDC) (adopted in September 1, 1987).

In the area of data development and management during FY 1987, OFCP staff initiatives included organizing and coordinating an ADAMHA Statistical Work Group to improve data collection; chaired meetings with State ADM authorities to identify ADM data needs and current State capabilities; automated administration of the ADMS and ADTR block grants; and developed a State Treatment and Prevention Leadership and Technical Assistance Strategy to improve Federal-State coordination.

In mid-FY 1988, the OFCP was transferred to the National Institute on Drug Abuse. The OFCP continues to carry out services and financing research initiated in FY 1987, and is modifying its FY 1988 agenda to focus on drug abuse services issues and the development of enhanced drug abuse data strategies.

## MINORITY ACCESS TO RESEARCH CENTERS

Question. How much funding is provided to the Minority Access to Research Centers (MARC) program by the NIMH, NIDA, and NIAAA research traing programs?

Answer. The information is presented in the following table.

ADAMHA MARC FUNDING BY INSTITUE
(Dollars in thousands)

| | 1987 Actual | 1988 Estimate | 1989 Estimate |
|---|---|---|---|
| NIHM.................. | $668 | $843 | $948 |
| NIDA.................. | 105 | 107 | 112 |
| NIAAA................. | 81 | 71 | 71 |
| ADAMHA Total.......... | $854 | $1,021 | $1,131 |

## OFFICE OF SUBSTANCE ABUSE PREVENTION

Question. Your justification states that the request for demonstration program funding within the Office for Substance Abuse Prevention (OSAP) will be sufficient to support third year continuation costs. If that is the case, why will only 83 of the 113 projects funded in 1988 be supported in 1989. Why will the average cost of a demonstration project jump by 14 percent from 1988 to 1989?

Answer. Of the 113 projects funded in 1988, only 83 requested and were approved for a third year of support. The increase in average cost per grant between 1988 and 1989 reflects the characteristics of this subset of grants that requested a third year of support. This subset consists of the more complex, ambitious projects that recognized, at the outset, their need for a third year of support to complete their demonstration program and hence requested a third year of support. With the smaller, less complex and, hence, less costly grants leaving the pool of funded grants, the average cost per grant would be expected to rise. Additional factors that explain an increase in the average cost per grant includes: (1) inclusion of an inflation factor in the budgets of many grants; (2) additional costs involved in data analysis and report writing at the conclusion of a project; and (3) additional costs in the last year of a project for the preparation of materials to disseminate the grant findings at conferences and meetings.

Question. Within the Office for Substance Abuse Prevention direct operations request, how much funding is assumed for each of the three initiatives -- prevention implementation, communications, and demonstration grants?

Answer. The 1989 budget request for direct operations includes the following estimates for contracts, personnel, and related support costs for the three OSAP initiatives:

Prevention Implementation: $5.7 million
Communications: $3.1 million
Demonstrations Programs (technical support and evaluation components): $3.5 million

The remainder of the direct operation request provides funds for the Office of the Director's coordination and leadership functions.

## ADMS BLOCK GRANT

Question. How many State compliance reviews does ADAMHA conduct annually for the Alcohol, Drug Abuse and Mental Health Services (ADMS) Block Grant ? How many reviews have been conducted to date for the special substance abuse block grant?

Answer. The Alcohol, Drug Abuse, and Mental Health Administration has conducted ADMS Block Grant compliance reviews at the following rate:

| | |
|---|---|
| FY 1982 | 5 |
| FY 1983 | 10 |
| FY 1984 | 10 |
| FY 1985 | 10 |
| FY 1986 | 8 |
| FY 1987 | 10 |
| FY 1988 | 6 Planned |

These reviews are conducted under the authority contained in the ADMS Block Grant, section 1918 (b)(1) of the Public Health Service Act, as amended by the Alcohol Abuse, Drug Abuse, and Mental Health Amendments of 1984, which requires that:

> The Secretary shall conduct in several States in each fiscal year investigations of the use of funds received by the States under this part in order to evaluate compliance with the requirements of this part and the certification provided under section 1916.

The ADTR Block Grant legislation does not contain similar language and therefor ADAMHA does not conduct compliance reviews concerning the utilization of funds.

## ST. ELIZABETHS HOSPITAL

Question. P.L. 98-621 authorized $30 million for the 1988 Federal subsidy for St. Elizabeths Hospital; the final 1988 appropriation was $28,722,000. Is the Federal Government legally required to provide $1,278,000 to make up the 1988 shortfall before the District of Columbia assumes full financial responsibility for the facility?

Answer. The transfer legislation, P.L. 98-621, did authorize a $30 million Fiscal Year 1988 subsidy payment to the District of Columbia a part of the financial transition for Saint Elizabeths Hospital. However, the Fiscal Year 1988 Appropriations Act, in implementation of the Bipartisan Budget Agreement applied a 4.3 percent reduction to the President's

Budget Request for the Hospital. This action legally established a lesser subsidy. No additional appropriation is legally required to make up the shortfall. Funds have been requested for the 1989 transition subsidy of $24 million for the District to facilitate the integration of the hospital into the District's mental health care system.

Question. Although it is authorized by P.L. 98-621, the Administration requests no further funding in 1989 for renovation of Saint Elizabeths Hospital facilities. Does the hospital concur with the Department's assessment that the Federal Government has fulfilled its responsibility in this area?

Answer. District officials, including those at the hospital, certainly desire additional Federal appropriations for capital renovations. We believe the Federal requirements under the law have been fulfilled in providing funds to make repairs and renovations to meet applicable code requirements and standards to the physical plant and support systems of the hospital which are to be utilized by the District's mental health system.

Question. Please describe the on-going Federal activities in the William A. White laboratory Building and other facilities on the Saint Elizabeths Hospital campus that have been retained by the Department.

Answer. Three Federal activities remain on the campus of Saint Elizabeths Hospital. As authorized in the transfer law, P.L. 98-621, we retain the William A. White building along with the adjoining animal facility for the conduct of intramural research. As you know, this research has been highly productive over the years, Its location on the grounds of the hospital predates the transfer of the hospital to the Institute. Currently the William A. White facility is engaged in basic research on special mental health problems such as aging and schizophrenia, and investigates normal and pathological processes in psychopharmacology and memory. Approximately 150 staff are assigned to the program, including 118 full-time permanent, 14 other than permanent, and about 14 visiting scientists and guest workers.

In addition, the Immigration and Naturalization Service/Public Health Service Evaluation and Detention Center remains on site on the St. Elizabeths Hospital grounds. Presently, the program is located on the west side in the Home and Relief buildings. All funds and positions for the program are provided by the Department of Justice. Mental health services to Cuban entrants were initiated shortly after the Mariel Boatlift in April 1980. Initially, services were directed toward supporting the sponsorship efforts in the various resettlement camps. Later, the need for an inpatient program was recognized and established on the grounds of St. Elizabeths Hospital, concurrent with a nationwide network of community-based residential treatment programs. The mental health services are provided to the Cuban entrant population by the Refugee Mental Health Program, NIMH, through a contract with a private firm. We expect the program to remain on the hospital grounds as long as the need exists and funds are enacted.

Finally, the Saint Elizabeths Hospital Museum, located on the second floor of the Center Building was retained on the Department's inventory because of its historical significance. Affiliated with the Smithsonian Institute, the museum displays and exhibits many antiques, portraits, and artifacts of interest on the 132 years of the hospital, including the desk Dorothea Dix used when she wrote the original draft of a law that established Saint Elizabeths as the first Federal institution for treating the mentally ill. Saint Elizabeths Hospital, founded in 1852 as the Federal Hospital for the Insane to serve residents of the District of Columbia and Federal beneficiaries, only recently devoted efforts to documenting its rich history.

## FTE LEVELS

Question. The Department requests almost a 60 percent increase in ADAMHA AIDS funding over the 1988 level, yet only 10 additional FTE. The non-AIDS portion of the ADAMHA request actually assumes a reduction of 5 FTE from 1988. How can a net increase of 5 FTE be adequate to staff the many new program responsibilities at ADAMHA?

Answer. In fact the non-AIDS portion of the ADAMHA request proposes a reduction of 15 FTE. This results in a net decrease in total FTE of 5 from 1,665 to 1,660. We believe that we can maintain functioning programs with the proposed level of staffing.

## RURAL MENTAL HEALTH

Question. Please provide a report on the findings of the four rural mental health demonstration projects funded at $1.2 million in the 1987 appropriations bills.

Answer. NIMH grant awards for the four rural demonstrations were issued in September 1987. Since that time, the four recipient States have recruited staffs, developed their demonstration plans in more detail, reached agreements with community agencies concerning these plans, and initiated some demonstration activities at State and community levels. Since the demonstrations and a related evaluation study are still in early stages of development, there are no findings to report at the present time.

## SERVICES DELIVERY RESEARCH

Question. Please indicate the amount of 1988 funding you have allocated for services delivery research for Alzheimer's disease. What types of projects have been funded?

Answer. Our Institute's level of support for mental health services research is estimated at $11.2 million for FY 1988. The National Institute of Mental Health currently is reviewing research applications for services research to the severely mentally ill. We expect many proposals to be relevant to the financing and delivery of mental health services to persons with Alzheimer's disease.

The Institute's program of mental health services research is concerned with mentally ill persons seen in both the general health care sector and the specialty mental health sector. Major program emphases are: studies on the delivery of services to the severely mentally ill, research on the role of the primary (medical) care system in the delivery of mental health services and issues in the financing and reimbursement of mental health care.

We expect to expand our research focus on Alzheimer's disease to include health services and treatment modalities relevant to the mental, behavioral, and psychological problems associated with Alzheimer's disease; and family stress and burdens associated with patient care.

## PROTECTION AND ADVOCACY

Question. What kinds of abuses of the rights of mentally ill persons have been found and reported through the Protection and Advocacy Program?

Answer. Protection and Advocacy Programs for the Mentally Ill reported serving a total of 9,758 clients in fiscal year 1987 with a total of 14,132 case problem areas. Reported client problems fell into three categories:

- Abuse allegations comprised 3,181 (22 percent) of the total case problems handled. The top four problem areas were: 1) inappropriate or excessive medical treatment; 2) inappropriate or excessive use of physical restraint, isolation, or seclusion; 3) physical assault; and 4) exploitation (financial, physical, or emotional).
- Neglect allegations comprised 6,426 (45 percent) of the total case problems. The top three problem areas reported were: 1) failure to provide adequate or appropriate medical/mental health treatment; 2) failure to provide discharge planning; and 3) failure to provide timely release from residential facilities.
- Other rights issues comprised 4,533 (32 percent) of the total case problems handled. Included were problems with obtaining financial reimbursements, and access to education and legal representation.

## MENTAL HEALTH DATA EXCHANGE

Question. The 1984 amendments to the Alcohol, Drug Abuse, and Mental Health Services Block Grant required the Department to cooperate with appropriate national associations to develop State data exchanges. We understand that although this was done in the areas of alcohol and drug abuse, it has not been accomplished for mental health. Why hasn't the Department entered into an agreement with a group, such as the

National Association of State Mental Health Program Directors (NASMHPD), to develop a model for State data exchange for mental health programs?

Answer. In fiscal year 1989, the National Institute of Mental Health (NIMH) is proposing to implement, in collaboration with NASMHPD, a State mental health data profile system. This system will include information on the organization, funding, operation, and services provided through the State mental health agencies. A feasibility study of such a system was completed in 1987 by NASMHPD, with NIMH funding. This system could meet the block grant data reporting requirements and provide valuable data for service systems research.

In addition to this specific activity, NIMH has a long history of working with the States individually, and through NASMHPD, to develop other models for State data exchange. Three current activities are important to mention:

- NIMH biennially collects information from the States through the Inventory of Mental Health Organizations and General Hospital Mental Health Services.
- The Mental Health Statistics Improvement Program, a cooperative Federal/State program designed to upgrade mental health statistical activities at all levels of the mental health services delivery system.
- Under a contract from NIMH, NASMHPD developed a methodology for compiling comparable data on State mental health agency allocation and expenditure of funds, and sources of revenue for mental health operations.

## ALCOHOL AND DRUG ABUSE CLINICAL TRAINING

Question. In the past, funds have been provided within the NIMH clinical training budget for a joint alcohol/drug abuse program. Please provide information on what types of activities are sponsored under this program.

Answer. The alcohol and drug clinical training program, funded within the NIMH clinical training program, currently supports contracts to develop and evaluate model programs of alcohol and drug training for health professionals. The clinical competencies which are addressed as part of the alcohol and drug training programs include the health care provider's role in prevention, routine screening, patient assessment and diagnosis, and patient management and relapse prevention. Contracts have been awarded to medical schools for these activities, and in 1988, the program has been expanded to include schools of nursing. The long-term goal of this program is to assure the integration of alcohol and drug training into the core curriculum of health professions education.

## ALCOHOLISM TREATMENT STUDY

Question. Please provide any preliminary findings that are available from the National Academy of Sciences study of alcoholism treatment that was commissioned in compliance with the Anti-Drug Act of 1986.

Answer. The National Academy of Sciences (NAS) does not provide preliminary findings of its studies. Its report is expected to be available by the middle of next year and will be transmitted to the Congress by the Secretary at that time.

The expert committee named by NAS to carry out the study met for the first time in September, 1987 and again in January of this year. The next meeting of the Committee is scheduled for May.

The NAS report is expected to provide recommendations on research, planning, administration, and reimbursement for treatment and rehabilitation of persons suffering from alcohol abuse and alcoholism. We anticipate the Academy's report will make a very significant contribution to public understanding of important clinical, scientific, and policy issues bearing on alcoholism treatment.

### HOMELESS DEMONSTRATIONS

Question. How many applications were received for homeless demonstration projects under the Stewart B. McKinney Homeless Assistance Act? How many were approved, but unfunded?

Answer. Thirty-three applications were received from State mental health authorities for mental health services demonstration projects under the Stewart B. McKinney Homeless Assistance Act. Nineteen of these were approved by a peer review committee in January 1988; 12 of these projects are being funded at this at time, leaving 7 approved but unfunded.

We received 88 applications for alcohol and drug abuse homeless demonstrations. Of the 88 applications, 45 were approved and 9 are being funded, leaving 36 approved but unfunded applications.

## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### CLINICAL TRAINING

Question. How many trained personnel in the various disciplines are needed with:

a. Seriously mentally disturbed adults
b. Seriously mentally disturbed children and adolescents
c. Racial, ethnic minority and disadvantaged populations

Answer. The data which are currently available on the number of trained personnel needed to serve seriously mentally ill adults and children and racial, ethnic minority and disadvantaged populations is not adequate or sufficiently current to cover the range of disciplines in the question.

The Office of Technology Assessment Report, Children's Mental Health Problems and Services, 1986 indicates that while there are approximately 5,000 clinical child psychologists, 7,000 child and family oriented social workers, and 1,000 child/family nurses, "Estimates of the number of professionals needed have consistently been much higher". The most recent data available is from a 1980 report of the Graduate Medical Education National Advisory Council which indicated a requirement for 9,000 child psychiatrists by the year 1990. Currently there are 4,000 child psychiatrists, reflecting a shortfall of 5,000.

To gather accurate needs assessment data concerning the seriously mentally ill adults, racial and ethnic minorities, and disadvantaged populations would require a study similar to that which was mandated by the Congress and provided in September 1987 by the HHS Committee on Personnel for the Health Needs of the Elderly. That report was able to state that, by the year 2020, the Nation will need 5,000 psychiatrists and 5,000 psychologists with specialty training in geriatrics and that the faculty needs to train these people would be 500 additional faculty in psychiatry and 900 additional faculty in psychology. It is estimated that currently there are less than 1,000 psychiatrists and psychologists who specialize in geriatrics.

Question. Payback of stipends received under the NIMH clinical training program has been required since 1981. Please indicate:

a. The numbers of students, by professional discipline, who have incurred a payback obligation since 1981.

b. The numbers of students, by discipline, who have completed their payback obligation; those still in the pipeline; and those who are delinquent.

Answer. In 1981, the concept of payback was introduced, so that trainees who had been supported by the NIMH Clinical Training Program for more than six months were required to work in the public sector for as many months as they received support. As of October 1, 1987, a total of 5,405 NIMH clinical trainees have incurred a payback obligation; of these, over 2,408 have already completed their payback service. NIMH expects that over 4,700 will finally do so. Approximately 13 percent will elect or be required to fulfill the monetary payback provision.

The breakdown by discipline is as follows:

| | Psych. Nursing | Psychiatry | Psychology | Social Work | Other | Total |
|---|---|---|---|---|---|---|
| A. No. of students who have incurred payback obligation | 1,199 | 142 | 2,157 | 1,797 | 110 | 5,405 |

| | Psych. Nursing | Psychiatry | Psychology | Social Work | Other | Total |
|---|---|---|---|---|---|---|
| B. No. of students who have completed payback obligation | 673 | 62 | 749 | 876 | 48 | 2,408 |
| No. of students who are still in pipeline | 454 | 75 | 1,287 | 781 | 55 | 2,652 |
| No. of students who are delinquent (must elect monetary payback) | 72 | 5 | 121 | 140 | 7 | 345 |
| Total under B. | 1,199 | 142 | 2,157 | 1,797 | 110 | 5,405 |

Question. The NIMH clinical training peer review committees were disbanded about 8 years ago. How have grant applications been reviewed since then?

Answer. In those years in which grant applications have been reviewed, the review has been carried out by ad hoc Special Training Committees, organized on a multidisciplinary basis around the substantive areas that were targeted in Congressional report language, such as the chronically mentally ill, aging, and children and youth.

Question. Since Congress increased the FY 1988 clinical training budget, what provisions are now being made for the reestablishment of clinical standing review committees?

Answer. The NIMH does not plan to reestablish standing clinical training committees. There are two variables which change from year to year: priority areas of substantive focus of training to be supported, and number of applications from each of the four core disciplines. These variables are considered in determining the composition of ad hoc Special Training Committee(s). A standing review committee would not provide the needed flexibility.

Question. What is the current NIMH administrative structure for the clinical training program, and how many professional staff with direct responsibilities for clinical training are assigned to the program.

a. How many support staff are assigned to the program?

b. What current vacancies exist in professional and administrative staffing for the program?

Answer. The NIMH currently has a three-part structure for administering the clinical training program, with two parts located in the Division of Education and Service Systems Liaison (DESSL) and one in the Division of Clinical Research (DCR). The State Planning and Human Resource Development Branch, DESSL, administers the Human Resources Development Program with two and one-half professional staff and one-half support staff assigned to the program. The Education and Training Branch, DESSL, administers the largest part of the NIMH clinical training program, with four professionals and one full time support staff assigned to it. The Mental Disorders of the Aging Branch, DCR, administers the NIMH clinical training program addressed to geriatric mental health; approximately one-half full-time equivalent professional staff and one-half full-time support staff are assigned to that program.

Two professional and one support staff vacancies exist in the Education and Training Branch, DESSL.

Question. Please indicate for FY 1987, the allocation of clinical training funds by discipline, and the proposed allocation by discipline for FY 1988?

Answer. The clinical training allocation for FY 1987 and the proposed FY 1988 by discipline is as follows:

Clinical Training
(dollars in thousands)

| Discipline | FY 1987 Actual | FY 1988 Estimate |
|---|---|---|
| Psychiatry | $3,078 | $3,389 |
| Psychology | 2,182 | 2,402 |
| Nursing | 1,948 | 2,145 |
| Social Work | 1,531 | 1,686 |
| Subtotal | 8,739 | 9,622 |
| Mental Health R & D | 938 | 1,033 |
| Multidisciplinary | 625 | 688 |
| Paraprofessional | --- | --- |
| D/ART | 520 | 786 |
| State Human Resources | 2,525 | 3,001 |
| NIAAA/NIDA Joint Training | 1,000 | 1,000 |
| Other Clinical Training * | 615 | 625 |
| Total | 14,962 | 16,755 |

*Other Clinical Training includes payback, evaluation and peer review costs.

Question. How were clinical training funds not allocated directly to the professional disciplines used in FY 1987, and proposed to be used in FY 1988?

Answer. The following mental health clinical training funds are used for activities other than direct training in the mental health disciplines:

| Activity | FY 1987 | FY 1988 |
|---|---|---|
| State Human Resource Development Program | $2,525,000 | $3,001,000 |
| Alcohol and drug abuse health professions education | 1,000,000 | 1,000,000 |
| Depression Awareness Recognition and Treatment (D/ART) | 714,000 | 786,000 |
| Service payback monitoring activities | 241,000 | 241,000 |
| Application Review and Program Evaluation | 179,000 | 179,000 |
| TOTAL | $4,659,000 | $5,207,000 |

Question. Four types of clinical training grants do not directly train service providers, nor do they result in payback requirements. These are: faculty development, curriculum development, state human resource development, and alcohol and drug abuse grants. What are the primary objectives and accomplishments regarding mental health personnel needs of these initiatives? What have they accomplished?

a. What evaluations of these programs have been conducted?

b. What has been the past effort (numbers of grants, dollars by discipline, priority populations served) over the past three fiscal years?

Answer.

Faculty Development

Faculty development grants were awarded in child mental health in FY 1986 and 1987. These awards (contrary to the question) do require payback if they are awarded for more than 180 days, and all such awards have met this condition.

The purpose of faculty development awards is to improve the teaching faculty of institutions which prepare mental health professionals in treatment services for the priority populations. These awards would be made to promising young individual faculty or potential faculty from social work, psychiatry, psychology, and psychiatric nursing to enhance teaching careers in the priority areas.

While informal reports indicate that the faculty development awards have accomplished their objectives, there has been no systematic evaluations of this program.

In FY 1985, there were no faculty development awards; in FY 1986, there were six child mental health faculty development awards--all in psychiatry, $218,000; and in FY 1987 there were two child mental health faculty development awards--both in psychiatry, $62,728.

Curriculum Development

In FY 1985, 1986, and 1987, the purpose of Research and Development (R&D) for Clinical Training Curriculum Development was to generate, evaluate, and disseminate new knowledge. Typically, such projects have been concerned with the development, evaluation, and dissemination of model curricula designed to be adaptable to other teaching sites. Such models are based on research or interventions which have empirical evidence of efficacy and are generalizable to other settings.

The FY 1986 Announcement, Research and Development Grants for the Improvement of Mental Health Services Training (MH 86-18), stated that these projects must address the following priorities:
(1) prevention intervention with high-risk populations or
(2) improving services to the chronically mentally ill, including those who are homeless; children and youth, with major emphasis on those who are at risk for serious mental or emotional disability; or refugee populations. Within these priority areas, emphasis is placed on training for service in underserved geographic areas and to underserved populations, e.g., rural and inner city populations, ethnic minorities and women, and training for effective community-based services, including psychosocial rehabilitation.

These R&D grants in curriculum development usually have built-in evaluation components. By their very nature, these grants are not uni-disciplinary. They are all multi-disciplinary.

| | # of Grants | $ Total | $ Prevention | $ Child | $CMI | $Refugee |
|---|---|---|---|---|---|---|
| FY 86 | 12 | $1,006 | $584 | $ 94 | $279 | $49 |
| FY 87 | 11 | $938 | $535 | $94 | $315 | — |
| FY 88 | 9 | $812 | $368 | $118 | $326 | — |

(dollars in $000)

State Human Resource Development

The overall purpose of this program has been to improve the capacity of States to increase the availability, accessibility, and competence of the State mental health services work force by determining work force requirements and improving structures, processes, and technology for recruitment, distribution, utilization, productivity, continuing education and training, and retention of personnel.

Some of the major recent accomplishments of the HRD program have been to develop effective training in mental health administration for mental health systems managers at the State and community level. HRD has also had an effective special initiative in the training of personnel to work with the mentally ill in jails The HRD program has historically developed and provided effective continuing education for direct service providers currently working with the most seriously mentally ill in the public mental health system. A comprehensive program review of HRD was carried out in fiscal year 1985. The program review generally concluded that the program has been very effective in improving better recruitment and retention practices in the States and in providing in-service training of professional mental health personnel currently in short supply in community-based systems of mental health care.

| Fiscal Year | Number of Grants | $ Total |
|---|---|---|
| 1985 | 41 | $3,522,012 |
| 1986 | 34 | $3,989,595 |
| 1987 | 30 | $2,525,000 |

Alcohol and Drug Abuse Clinical Training

The clinical training programs of both NIAAA and NIDA were discontinued in 1982, but the continuing need to improve the alcoholism and drug abuse treatment capabilities of health professionals has led to a Congressional directive to support efforts in this area within the funds appropriated for mental health clinical training. Therefore, the current program was begun in 1985 when $.5 million was allocated to a joint NIAAA and NIDA health professions education program. In both 1986 and 1987, $1.0 million were earmarked for this purpose.

These funds have allowed the two Institutes to award contracts to medical specialty groups to assess training needs; develop guidelines for a comprehensive education strategy; and develop and disseminate resource guides to their members. The specialty groups involved in the program have included pediatrics, family medicine, psychiatry, general internal medicine, emergency medicine, obstetrics and gynecology. In addition, contracts have been awarded for development and evaluation of model programs of alcohol and drug training in family medicine, general internal medicine and pediatrics.

The goal of the current program and the goal for the future activities is to assure that alcohol and other drug abuse training is incorporated into the curricula of health professions educational institutions. Unlike the training required to deal with some health problems, the major unmet need is for all health professionals to be knowledgeable in the identification and treatment of alcohol and other drug abuse.

Question. What are your plans for the clinical training program in FY 1989 assuming that the Congress appropriates additional funding of (1) $17 million, (2) $20 million or (3) $25 million?

Answer. It is the Administration's position that we have now reached the point where Federal support for clinical training is no longer needed, in large part due to NIMH's past success. An overall national shortage of Mental Health professionals no longer exists.

It is premature to state or predict how NIMH would expend additional funding since offsets have not been identified consistent with The Bipartisan Budget Agreement. It would depend on the level of appropriation and the number of quality applications received.

The Administration believes that this program can be phased out over a three year period, with responsibilities transferred to States, colleges, and universities to appropriately train our future mental health professionals to meet the needs of the most seriously mentally ill.

### MINORITY FELLOWSHIP PROGRAM

Question. In 1987, the NIMH awarded a Minority Fellowship Program grant to the American Psychological Association for the training of minorities in the neurosciences. I understand, however, that the amount awarded ($227,000) is substantially less than the amount requested and approved during NIMH peer review of the grant application, and that the program's ultimate success could be compromised by the result. Please tell me what is being done to correct this situation, and what is the planned FY 1989 allocation for the Minority Fellowship Program in Neurosciences.

Answer. In FY 1988 the planned award (for direct costs) to the American Psychological Association for this important activity will be $277,000. The current FY 1989 allocation is for $295,000. If additional funds become available the level of the FY 1989 award could be higher.

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## QUESTIONS SUBMITTED BY SENATOR DALE BUMPERS

### RESEARCH GRANTS

Question. The Administration is proposing that NIMH issue about 10 percent fewer new/competing research grants in FY 1989 than in FY 1988. What is the rationale for proposing this reduction? Aren't there plenty of very good research ideas to pursue?

Answer. Overall we will fund more research grants than in either 1988 or 1987. In fact, we will fund the highest level in our history. Our dollar allowance is an increase of about 5 percent at a time when the general increase agreed upon between the President and the Congress for the Federal government is 2 percent. The number of new grants has decreased within this overall increase because of the expansion of our commitment base. The number of these continuations is up from last year because of increases in new grants in the last two years.

Question. The administration is proposing a decrease in funds from NIDA research grants. Is this wise considering the huge problem that exists in this country today with drug abuse?

Answer. If the funds requested for NIDA's AIDS related drug abuse activities in the PHS consolidated AIDS budget are included, the total NIDA budget increases by over $40 million, or more than 20 percent. The combined research budget remains essentially the same, rather than decreasing the apparent $3.7 million reflecting a small shift in priorities in favor of demonstrating immediately needed drug abuse services for what has become the Nation's number one health issue.

The Administration places a very high priority on prevention and control of drug abuse. In total for these activities, this budget provides a significant 14 percent increase, from $523 million to $596 million.

The apparent reduction in the NIDA account relates only to its research line and is a result of the manner in which the current budget is displayed and historical obligation patterns, not a lessening priority.

A large $27 million increase was provided in the 1987 Substance Abuse Initiative supplemental for NIDA. The sizable infusion of new money in FY 1987 created an approximately 50 percent expansion in the NIDA commitment base in FY 1988 which is now declining as funding stabilizes. This is the major factor in the decline since NIDA has 43 fewer non-AIDS continuation grants in 1989 totaling about $5 million.

### CLINICAL TRAINING

Question. The Administration is proposing to reduce NIMH clinical training program from $16.8 million in FY 1988 to $10.0 million in FY 1989. This program has sought to attract mental health professionals into the service of such underserved groups as the elderly, emotionally disturbed children, individuals with schizophrenic disorders. Since the National Mental Health Association contends there is still a big need for people to enter this area of mental health work, I think this is the wrong time to be cutting this program. Is the Association wrong about the need?

Answer. We feel that the capacity of the mental health education system to train such mental health professionals is sufficient to meet this need. Concurrently, the Administration feels that resources are available to support the training of these potential mental health professionals. The budget proposal allows three years for the educational systems and students to adjust to the shift away from direct federal training programs.

### CAUSES OF SCHIZOPHRENIA

Question. You have indicated in the material that you have provided the committee that you have developed a National Plan for Research on Schizophrenia. Also, a significant portion of your research funds are being used to develop a better understanding of this disease. Can you give the committee a summary of the current thinking about the causes of schizophrenia?

Answer. The current thinking about the causes of schizophrenia emphasizes the interaction between genetic and environmental components. Research on the genetics of schizophrenia has uncovered chromosomal candidates for study using the most current techniques of molecular biology. Because the manifestations of schizophrenia may be the final common pathway originating from several etiologies, the genetic disturbance in one pedigree may differ from that in another. Environmental influences may trigger the manifestation of the genetic defect. These events may include exposure of the pregnant mother to viral agents, such as is suspected for some Finnish schizophrenic patients. Birth traumas of various varieties have also been implicated as catalysts of schizophrenia. The most recent hypothesis suggests that the genetically at-risk-for-schizophrenia fetus is particularly susceptible to the influence of environmental stressors (e.g., flu) during the second trimester of gestation. The resultant disorder, which appears most often in early adulthood, is characterized by behaviors which may be mediated by the neurotransmitter dopamine. Treatment of the symptoms of schizophrenia by dopamine blocking agents is effective in relief for certain schizophrenic symptoms. These same medications also appear to decrease the likelihood of relapse. Some symptoms of schizophrenia may be caused by structural abnormalities in the brain, while other symptoms appear due to neurochemical dysfunction. Research on molecular genetic and neurodevelopmental approaches to the causes of schizophrenia is being stimulated by NIMH grants, workshops, etc.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### BUDGET REQUEST

Question. Mr. Trachtenberg, what was your original budget request to the Department? What was the Department's original request to the OMB and how does it differ from the request before the Subcommittee?

Answer. Our request to the Department totaled $1,386,424,000 which included $171,617,000 for AIDS activities and $24,000,000 for St. Elizabeths Hospital. The Department's original request to the OMB totaled $1,288,386,000 which included $171,617,000 for AIDS and $24,000,000 for St. Elizabeths Hospital. The request before the Subcommittee would total $1,528,413,000 if the $177,617,000 for AIDS requested in the OASH budget and the $24,000,000 for St. Elizabeths Hospital were included.

### NEUROSCIENCE RESEARCH TRAINING

Question. Dr. Judd, at my request, this Committee asked the Director of the National Institute on Mental Health and the Director of the National Institute on Neurological and Communicative Disorders to report on coordination of Research in the Neurosciences and Mental disorders. The report, which was forwarded to the Committee in February, made four specific recommendations:

- Enhance the current research training programs of the NIMH and NINCDS and the coordination of NIMH and NINCDS programs of basic and clinical neuroscience research training to address the biomedical issue of neurological and mental disorders, including schizophrenia;
- Initiate regularly scheduled meetings of the Directors of NIMH and NINCDS to increase the coordination of future research and research training activities;
- Officially designate a liaison member from each Institute to the other Institute's National Advisory Council; and
- Increase the human brain banking facilities which are co-funded by the NINCDS and the NIMH.

I am particularly interested in the recommendation to enhance and coordinate research training programs between NINCDS and NIMH. Can you tell me how this recommendation will be implemented and how much has been requested for such training in the FY 1989 Budget Request?

Answer. A specific amount has not been set aside in the FY 1989 budget request. Currently, the two Institutes are exploring the drafting of a joint announcement for applications concerning neuroscience research training and AIDS. We are also encouraging research training applications from sites that have grants from the two Institutes. I am sure that through the regular meetings between Dr. Goldstein and myself, we will be able to identify additional opportunities for our two Institutes to pursue in the area of research training. It is especially important to us to know that this is an area of which you are particularly interested.

## BLOCK GRANTS

Question. Mr. Trachtenberg, you have been quoted as suggesting that ADAMHA block grants, including the "recent alcohol and drug (abuse) block grant programs," could be shifted to the Health Resources and Services Administration, a move you admitted might be "controversial."

You are also quoted as having said that block grants "are basically funding instruments; there is very little programmatic aspect that is attached to them" . . . and that the ADAMHA institutes should "resist classic service-type activities" that are not scientifically based and avoid funding demonstration programs that are actually services programs.

Mr. Trachtenberg, don't you think it is important to administer these block grant programs from the agency that has the particular expertise in mental health, alcohol and drug abuse?

Answer. The Alcohol, Drug Abuse, and Mental Health Administration Block Grant programs have been administered since their inception in accordance with statutory and administrative intent to provide States maximum flexibility in using Federal funds to meet their ADM prevention and treatment needs. ADAMHA's oversight of State Block Grants has focused on ensuring that States are in compliance with the law. In addition, we have taken the opportunity to provide both program and management technical assistance to States during our on-site compliance review activities.

The Alcohol, Drug Abuse, and Mental Health Administration intends to enhance it's ability to help States and service providers improve prevention and treatment activities through increased transfer of knowledge gained from our research and demonstration activities and helping States share information of value. Indications are that the States continue to welcome the opportunity to work in a collegial manner with us in the provision of technical assistance and knowledge transfer.

In the context of technical assistance, ADAMHA believes that it is important to administer the Block Grant programs from the agency that has the particular ADM expertise.

## CHILD AND ADOLESCENT DISORDERS

Question. Dr. Judd, according to research scientists at NIMH, approximately 13 to 18 percent of persons under 18 experience mental disorders at any given time. I agree with the scientists who have said that "if these more than eight million affected children and adolescents continue into adulthood with chronic disorder, the magnitude of the problem is enormous." (p. 51)

What kinds of research is the NIMH conducting regarding Child and Adolescent Disorders?

Answer. The Institute is undertaking research on all aspects of child and adolescent disorders. These disorders include autism, attention deficit disorder, conduct disorder, affective disorders, anxiety disorders, eating disorders, learning disorders, and mental disorders associated with mental retardation and with somatic illness, and Tourette's syndrome. A high priority has been placed on youth suicide research. The DHHS Secretary's Task Force on Youth Suicide submitted a multi-volume report on youth suicide that covers the scope, risk factors, prevention and interventions, and strategies for the future on this issue. Many of the Task Force recommendations on research have been incorporated into Institute program areas, coordinated by an Institute-wide Suicide Consortium.

The Child and Adolescent Disorders Research Branch provides support for research in the phenomenology, etiology, genetics, diagnosis, classification, longitudinal course, outcome, treatment (psychosocial and psychopharmacological) and rehabilitation of the mental disorders and clinical problems of children and adolescents including youth suicide through 18 years of age.

The wide spectrum of NIMH intramural programs relevant to children and youth include research with the following: obsessional disorders of childhood, psychiatric disorders of children and disorders in their parents and environments, interrelationships between pubertal development and psychosocial functioning, diagnosis in child psychiatry, studies of learning and memory disabilities, eating disorders, dietary and pharmacological studies, children at risk for schizophrenia, hyperactivity, attention deficit disorders, and inborn errors of metabolism such as Tay Sachs and Gaucher's disease.

Question. Dr. Judd, in your professional opinion are we spending enough money on research in child mental health?

Answer. Child and adolescent mental disorders are an area of particular concern to me. It has become clear to me, in the four months since my becoming Director, that this is a field that needs special attention. The issue is that many mental health researchers tend to shy away from this area because it is an extremely difficult one in which to work. We believe that we need to develop a cadre of child and adolescent mental health researchers and encourage the field to concentrate on childhood mental disorders. To accomplish this, the NIMH has sent a descriptive summary of all available funding mechanisms to the directors of 130 child psychiatry residency training programs. The Institute has established a Child and Adolescent Mental Health Academic Award to train more researchers. The NIMH has also contracted with the Institute of Medicine to do an in-depth analyses of the child and adolescent mental health field to identify opportunities, needs, and to recommend courses of action.

## SUPPLY OF MENTAL HEALTH PROFESSIONALS

Question. Dr. Judd, the NIMH budget justification states that "The enhancement of mental health education capacity of colleges, universities, and medical schools for the purpose of training mental health professions has been successfully completed and allows us to phase the (clinical training) program over." (p. 79)

Dr. Judd do you really believe we have an adequate supply of mental health professionals trained to meet the needs of the long-term mentally ill; of children, adolescents, and elderly when:

- o suicide ranks as one of the leading causes of death among young persons aged 15-24
- o by the year 2000 as many as 2.4 million Americans will be diagnosed as suffering from Alzheimer's disease or other severe dementias
- o patients with schizophrenia occupy over 30 percent of the nation's mental hospital beds

Answer. Certainly, the mental health problems you have highlighted must be addressed by the State and local mental health programs of this country. Furthermore, it is correct that in many areas of the country there are not sufficient mental health personnel to attend to the elderly, to children and adolescents, and to those with schizophrenia.

However, the Administration feels that the capacity of the mental health education system to train such mental health professionals is sufficient to meet these needs. Concurrently, the Administration feels that resources are available to these potential mental health professionals to the point that they do not have to depend on funds from the NIMH.

## NIAAA STAFFING

Question. Dr. Gordis, while the President's budget request proposes an increase of $13.6 million in the non-AIDS budget for the National Institute on Alcohol Abuse and Alcoholism, it proposes a cut in full-time staff positions allocated to the Institute.

While I realize the proposed cut is only one FTE position, shouldn't your FTE positions increase with a funding increase of more than $13 million?

Answer. We believe that we can maintain viable programs of research and training with the proposed level of staffing.

Question. How many FTE's did you request with your original budget request?

Answer. The Institute's original budget request included 33 additional FTE's for NIAAA. Of the 33 FTE's, 20 were requested to fill staffing needs of the intramural research laboratories. The remainder were requested to fill gaps in staff expertise needed by the extramural programs, including the recently established programs for homeless demonstrations and treatment outcome research.

## NIDA RESEARCH PROJECTS

Question. Dr. Schuster, the American Psychiatric Association reports that under the President's budget 53 fewer research projects at the National Institute on Drug Abuse will be awarded in 1989 than in 1988.

Is this correct?

Answer. Not exactly. This reduction in the non-AIDS research portfolio is due to a complex set of stabilization policies and the size of the commitment base generated by the substantial increases NIDA received in FY 1987. The total number of research projects to be awarded by NIDA, including AIDS projects, in FY 1989 will be nearly the same as in FY 1988.

Question. How do you justify such a cut in research projects and research funding at a time when more information and research is needed, not less?

Answer. If the funds requested for NIDA's AIDS related drug abuse activities in the PHS consolidated AIDS budget are included, the total NIDA budget increases by over $40 million, or more than 20 percent. The combined research budget remains essentially the same, rather than decreasing the apparent $3.7 million reflecting a small shift in priorities in favor of demonstrating immediately needed drug abuse services for what has become the Nation's number one health issue.

The Administration places a very high priority on prevention and control of drug abuse. In total for these activities, this budget provides a significant 14 percent increase, from $523 million to $596 million.

The apparent reduction in the NIDA account relates only to its research line and is a result of the manner in which the current budget is displayed and historical obligation patterns, not a lessening priority.

A large $27 million increase was provided in the 1987 Substance Abuse Initiative supplemental for NIDA. The sizable infusion of new money in FY 1987 created an approximately 50 percent expansion in the NIDA commitment base in FY 1988 which is now declining as funding stabilizes. This is the major factor in the decline since NIDA has 43 fewer non-AIDS continuation grants in 1989 totaling about $5 million.

## BEHAVIORAL SCIENCE RESEARCH

Question. I am told that of all the research conducted through the NIH and through ADAMHA, only 2 percent is Behavioral Science Research. Is that correct?

Answer. The Alcohol, Drug Abuse, and Mental Health Administration does not code it's research by discipline. The only available data relevant to answering this question come from that submitted for and published in the National Science Foundation report, Federal Funds for Research and Development: Fiscal Years 1985, 1986, and 1987. This is the most recent edition of the

Report. From figures found in Vol. XXXV, defining "behavioral science" as research in psychology and in the social sciences, we calculate that in FY 1987 ADAMHA spent 37.5 percent of its research dollars in the behavioral sciences, and that NIH spent 1.9 percent.

Question. Given that the Surgeon General, the Secretary of HHS and just about every other public health expert in this country has stated that changing behavior is the primary way to stop the epidemic of AIDS, don't you think we should be spending more on behavioral science?

Answer. The Alcohol, Drug Abuse, and Mental Health Administration recognizes the need for a substantial portion of its research portfolio to consist of behavioral research. ADAMHA Is the leader is this area and is also aware of specialized needs, such as the AIDS crisis. For these reasons, over one-third of the overall ADAMHA research budget in FY 1987 was awarded to behavioral scientists. With respect to AIDS, ADAMHA is particularly cognizant of the importance of research on behavior. For example, the behavioral sciences portion of the NIMH budget for AIDS in FY 1988 is $8.3 million or 32 percent of the total of 26.2 million. Of this, approximately $5 million consists of research in behavioral change. In FY 1989, $15 million or 37.5 percent of the total AIDS budget of $40 million consists of research in the behavioral sciences with a major proportional increase directed to research in behavioral change.

Question. What percentage of total AIDS research dollars at NIMH was spent on behavioral science in 1987? What percentage in 1988?

Answer. The total NIMH AIDS research budget for FY 1987 was $11.3 million. That figure includes the $1.9 million Intramural Research Program budget which focuses almost exclusively on studies of central nervous system effects of HIV infection. Approximately 43 percent of the total FY 1987 AIDS research budget was spent on behavioral science studies. For FY 1988, we anticipate that approximately 53 percent of the total $26.2 million AIDS research budget will be spent on behavioral science research. This increase is a result of an increased number of projects and the funding of a research center for more than a one year period as a result of a shortfall in FY 1987.

Question. And of the amount spent on behavioral science, how much of this is spent on sexual behavior?

Answer. In FY 1987, $4.9 million was spend on AIDS behavioral science research, of which approximately $2 million was spent on issues related to sexual behavior. Correspondingly, in FY 1988, an estimate of $10.65 million will be spent on AIDS behavioral science research. This includes approximately 50 percent of the AIDS budget for research centers budget. Of this amount, roughly $4.26 million or 40 percent will be allocated to research on sexual behavior.

Question. In fact, has a comprehensive study on sexual behavior been done since the Kinsey report?

Answer. In 1970, Dr. Albert D. Klassen conducted an NIMH-supported study on sexual behavior for the Kinsey Institute. That study surveyed 3,108 men and women about sexual attitudes and behaviors, including inquiries about homosexual behavior. Data from that study may provide important information for planning AIDS research and programs. The Kinsey Institute is currently providing the data from the 1970 study to "qualified scientists." The National Institute on Child Health and Human Development is currently funding the development of research protocols for large scale studies of sexual behavior of children/adolescents and of adults.

## AIDS-RELATED DEMENTIA

Question. Have any studies been conducted to determine whether standard medications used for mental disorders have any special effect on someone who is seropositive or someone who has AIDS? In other words, when treating AIDS-related dementia with certain kinds of medication, could there be certain adverse effects unique to AIDS that should be monitored and evaluated?

Answer. Anecdotal reports and clinical experience indicate that HIV seropositive individuals can have enhanced sensitivity to psychoactive drugs (e.g., antidepressants and tri-cyclic antiemetics). Therefore, it is recommended that use of these drugs in seropositive individuals be at substantially reduced dosages and for longer periods of time to achieve clinical effect. Similar measures are also necessary in the elderly, and recommended dosages in HIV seropositive patients approximate those recommended for the elderly.

The only identified agent in the treatment of AIDS-related dementia is AZT. Its principal adverse effects are on bone marrow. As other drugs demonstrate adverse effects on AIDS dementia, it is quite likely that CNS effects and side effects will emerge. We strongly recommend the inclusion of CNS outcome measures to monitor these possible side effects in all anti-HIV drug trials.

NIMH is currently supporting one research project that will begin to answer questions about the effects of a psychotropic medication on ARC patients. Dr. Allen Frances, Cornell University Medical College, is studying the antidepressant treatment of AIDS-related depression with a randomized double blind placebo controlled trial of imipramine. The study began in July 1987 and findings are not yet available from this project. NIMH is interested in supporting further research to investigate the effects of psychoactive medications on seropositive individuals to determine whether psychoactive medications have any adverse impact on the progression of HIV-spectrum disorders and AIDS.

Question. What kind of training is the Public Health Service providing to insure that clear distinctions are made between a diagnosis of depression for someone with AIDS and a diagnosis of AIDS-related dementia?

Answer. While the later signs and symptoms of AIDS-related dementia are relatively easy to differentiate from depression, the early signs and symptoms are more difficult to differentiate, not only from depression, but from other medical disorders as well. Because the treatment and prognostic implications for these various disorders are so different, an important aspect of the NIMH AIDS education program is the education of health care providers to address this differential diagnostic issue. This is especially true for psychiatrists and other physicians, but other health care providers must be trained consistent with their background and role in service delivery. The training is conducted in a variety of ways, including lectures, small group teaching, video demonstration, and bedside rounds.

## AIDS RESEARCH TRAINING

Question. I was pleased to see the FY 1989 budget request included plans to fund AIDS research training programs in ADAMHA. Exactly how much will be spent in FY 1989 on AIDS research training? How much did you originally request? How much of the President's request will go toward training in the behavioral sciences area?

Answer. The President's budget requests $2,357,000 for ADAMHA AIDS research training within the consolidated AIDS budget proposal in the Office of the Assistant Secretary for Health. This is the same amount as was requested in our budget submission to the Department. While this is the first proposal for AIDS research training, our experience with AIDS research is that approximately 37.5 percent of total is spent in the behavioral sciences. The exact amount that will be spent on behavioral sciences research training will depend on the quality of the proposals from those fields.

## ALCOHOL'S ROLE IN AIDS

Question. What kind of AIDS studies are conducted to determine what role alcohol may play in the acquisition and spread of AIDS?

Answer. NIAAA is supporting both biomedical and behavioral studies on the role alcohol may play in the acquisition and spread of AIDS.

At the level of basic biomedical research, projects are underway to study the effects of alcohol on the cellular and humoral components of the immune system, the development of immune competence, and the molecular mechanisms of alcohol effects on the immune system.

There are striking similarities between the immune disfunction caused by chronic and excessive drinking and those observed after HIV infection. For example, chronic alcoholism has been found to cause a decrease in antibody response and this effect is likely to lead to decreased resistance to HIV infection. Furthermore, the T-lymphocyte population has been shown to be particularly susceptible to alcohol and this same cell type, crucial to the functioning of the entire immune system, is severely damaged in AIDS patients. Therefore, alcohol-caused alterations in the function and/or development of immunocompetent cells is under investigation. The influence of alcohol on the host resistance to infections in relation to an increased occurrence of opportunistic infections in alcoholic patients with AIDS is also an important area for AIDS research.

Studies on the influence of maternal drinking on the development of the immune system and on the transfer of immunocompetence from mother to child is another area of active research. Such studies will help to clarify some of the unknown factors for the acquisition of pediatric AIDS.

Additional research is conducted to study the biological and molecular mechanisms underlying the effects of alcohol on the immune system. Such studies will help us to understand, at the molecular level, how alcohol may increase the susceptibility to HIV infection, contribute to the type and severity of opportunistic infections and/or affect the course and treatment of the disease process. Basic knowledge in this area will help to provide the basis for formulating preventive and therapeutic strategies.

In the behavioral area, the Institute is supporting epidemiological studies on the relationship between alcohol and unsafe sexual practices which may lead to increased risk of infection with the AIDS virus in both the homosexual and heterosexual populations.

Question. How many of these studies look at how, by suppressing the immune function, alcohol may potentially increase the risk of developing AIDS?

Answer. The NIAAA supported 14 active grants in FY 1987 investigating the direct effects of alcohol on the immune function. These projects focus on the effects of alcohol on several components of the immune system and, in particular, on how alteration of the immune response due to acute or chronic alcohol exposure can play a role as cofactor in the development of AIDS and AIDS related complex (ARC).

The Intramural Research Program is carrying on several studies clarifying the general parameters of immunocompetence and investigating the effects of alcohol and other drugs on lymphocyte function as measured by lymphokine production and response to mitogens. Investigations are focusing on the proportions of T and B lymphocytes in the circulation of alcohol-treated animals and the relative proportions of helper and suppressor T cell subsets present in response to viral challenge. Intramural researchers have found that animals that are chronically treated with alcohol have a significantly reduced number of lymphocytes in the peripheral blood, spleen, and thymus. Furthermore, the remaining lymphocytes in these animals have impaired ability to proliferate in response to mitogens and antigens.

Question. And how many look at how inebriation may result in risky behaviors that may include those that increase the risk of infection with the AIDS virus?

Answer. Several preliminary studies are being conducted through a single award to the NIAAA-supported Alcohol Research Center located in Berkeley, California. These epidemiologic studies are developing baseline data on the relation between drinking and unsafe sex practices in several sub-groups of the population. To date, data has been collected on homosexuals and heterosexuals frequenting "singles" bars in San Francisco. One major finding of these studies suggests that persons who have consumed more than five drinks and had sex, engaged in unsafe sexual practices. Additional studies are projected to expand these data to a more representative population.

### AIDS-RELATED DEMENTIA

Question. More and more attention is being focused on dementia and other neurological symptoms sometimes associated with AIDS. How common is AIDS-related dementia and what are we doing to train our health professionals to diagnose this symptom?

Answer. We know that HIV infects the brain directly and secondarily. An estimated 80 percent of AIDS patients have organic impairment by death. However, symptoms vary widely in degree and kind. Research is ongoing to study the natural history of central nervous system effects of HIV infection, including the extent to which neuropsychiatric impairment is present in early HIV infection. Work is also ongoing to develop measurements to assess cognitive impairment due to HIV infection.

NIMH supports 21 contracts to train health care providers in mental health aspects of AIDS. This training includes attention to the diagnosis and treatment of AIDS-related dementia. In addition, NIMH has developed two publications focusing on neuropsychiatric complications of HIV infection. Neuropsychiatric Impairment Due to HIV Infection is directed towards nonmedical therapists and counselors, and How the AIDS Virus Affects the Brain was developed for friends, family, and "hand-on" caregivers.

Question. What impact does this development have on the kind of services needed by an AIDS patient?

Answer. While the NIMH does not provide direct mental health services to patients, the NIMH is currently supporting a contract to assess the mental health costs for persons with AIDS who also have cognitive disorders. This study, conducted with persons with AIDS who either are now or previously were on Maryland Medicaid rolls, will delineate the types and charges for services necessary to treat AIDS-related dementia.

Question. What are we doing to provide the mental health services needed by those who have AIDS-related dementia?

Answer. The NIMH does not provide direct mental health services. However, the NIMH is supporting research to delineate the natural history and extent of neuropsychiatric impairment related to HIV infection, as well as research concerning both the costs and efficacy of treatment for the various neuropsychiatric sequelae of AIDS and HIV-spectrum disorders. The Division of Biometry and Applied Sciences, NIMH, is planning a workshop to address the state of the art services research and to set a future agenda for a full range of AIDS and HIV related mental health services research.

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## QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

### COSTS OF MENTAL HEALTH CARE

Question. What is the total cost of mental health care?

Answer. The total costs to society of mental illness greatly exceed current spending on prevention and treatment. The estimated total cost of mental illness in 1980 was $54.2 billion. Of that amount, nearly $21.0 billion was spent for treatment services including long and short-term hospitalization and outpatient services and $2.6 billion was spent for supportive treatment services. In terms of indirect costs, $18.5 billion was attributable to lost employment due to incapacitation and disability. (Source: "Economic Costs to Society of Alcohol, Drug Abuse and Mental Illness, 1980." Report submitted by Research Triangle Institute to the Alcohol, Drug Abuse and Mental Health Administration under contract number ADM-283-83-0002). These figures are being updated by Dr. Dorothy Rice at the University of California, San Francisco, under an ADAMHA contract.

Question. What is the total cost of mental health care to the Federal Government (Medicaid, Medicare, V.A., Social Security Disability, SSI, etc.)?

Answer. For FY 1983 the costs for selected Federal Government programs to support and care for mentally ill persons were as follows:

| | |
|---|---|
| Medicaid | $1.2 billion |
| Social Security income program | $1.7 billion |
| Social Security disability insurance program | $1.3 billion |

In 1981, Medicare expenditures for mental health services amounted to approximately $1 billion.

For the Veterans Administration, the most recent (1980) estimates about $1.5 billion expended for mental health services.

Question. What is the total cost of mental health care to States?

Answer. In fiscal year 1985 approximately $8.3 billion was expended by State mental health agencies (SMHA). In constant dollars, i.e., adjusted for inflation, this represented a decrease of 0.4 percent from expenditures in fiscal year 1983. The total per capita expenditure in fiscal year 1985 ranged from a low of $8.38 to a high of $90.12. State expenditures included state mental hospitals, community based programs, and SMHA support services. State hospitals accounted for an estimated 64 percent of total 1985 expenditures.

Of these expenditures approximately $390 million represented State match Medicaid funds to the SMHAs. Five SMHAs are not able to report this amount because of unique accounting or appropriation processes in the State. For fiscal year 1983, the only year such data are available, approximately $618 million was expended in State Medicaid payments by other State agencies, i.e., non-SMHA agency expenditures. This figure could be projected to fiscal year 1985 as an approximation of other Medicaid expenditures for that year.

Sources: "State Mental Health Agency Revenues and Expenditures for Mental Health Services: Trends from 1981 to 1985." Chapter 6 and "State and Federal Expenditures for Mental Health Services, United States, 1983." Chapter 5 in Mental Health, United States, 1987, DHHS Publication Number (ADM) 87-1518, and Funding Sources and

*Expenditures of State Mental Health Agencies; Fiscal Year 1985* published by the National Association of State Mental Health Program Directors, 1987.

Question. What is the total cost of mental health care to cities and local government?

Answer. At this time it is not possible to estimate total costs of mental care provided by urban and local governments. A contract was recently let by NIMH to develop county level cost estimates.

Question. What is total cost of mental health care to business and industry?

Answer. The total private sector expenditures on mental health care were estimated at $5.5 billion dollars in 1980, divided roughly equally between private third party payments and out-of-pocket payments. Exact figures for direct costs to employers are not available.

The cost of reduced productivity among the currently employed in the U.S. due to mental illness was estimated to total $3.1 billion in 1980. Accurate data on private spending for mental health services is not available.

These figures are being updated by Dr. Dorothy Rice at the University of California, San Francisco, under an ADAMHA contract. In 1979, health insurance premium income of all private insuring organizations totalled $66.1 billion but no data is available on how much of this premium income can be attributed to mental health coverage.

(Source: "Economic Costs to Society of Alcohol, Drug Abuse and Mental Illness, 1980." Report submitted by Research Triangle Institute to the Alcohol, Drug Abuse and Mental Health Administration under contract number ADM-283-83-0002). (Source: 1980-1981 Source Book of Health Insurance Data. Health Insurance Institute. Washington, D.C.)

## MENTAL HEALTH SERVICES RESEARCH

Question. How much is NIMH spending on services research and how has that amount changed since 1980? What percent of the total cost of mental health is spent on services research?

Answer. In FY 1988, the Institute anticipates spending $11,208,000 on mental health services research. This is an increase of 165 percent from the $4,225,000 that was spent in FY 1980. Given the cost of mental illness in 1983 was estimated to be $72.8 billion, the amount that is being spent on services research is below one tenth of one percent.

Question. What percentage of NIMH's research budget has gone for mental health services research since 1980?

Answer. Most NIMH support of mental services research is in the form of grants awarded by the NIMH Division of Biometry and

Applied Sciences (formerly NIMH Division of Biometry and Epidemiology). The following table presents annual data on Division grant expenditures and the corresponding percent of the total NIMH research grant dollar.

| Fiscal Year | Expenditures Mental Health Services Research | Percent of NIMH Research Budget |
|---|---|---|
| 1980 | 0.44 | 0.4% |
| 1981 | 1.22 | 1.3% |
| 1982 | 2.68 | 3.1% |
| 1983 | 3.21 | 3.5% |
| 1984 | 3.53 | 3.2% |
| 1985 | 3.28 | 2.6% |
| 1986 | 4.63 | 2.0% |
| 1987 | 6.27 | 2.5% |

The above data do not include funds expended for mental health services research in the form of grants supported by the NIMH program on the aging, research contracts, and evaluation studies of NIMH services demonstration projects.

The current NIMH Director, Dr. Lewis L. Judd, has identified treatment and services research as on of three Institute research priorities. Support for mental health services research will increase in FY 1988 as a result of NIMH funding of four new Centers for Research on the Organization and Financing of Services for the Severely Mentally Ill.

Question. What is planned for FY 1989? Is this amount adequate or what amount is needed to make more cost effective use of existing Federal, State, and local expenditures for mental health care?

Answer. NIMH currently plans to allocate about $9 million in FY 1989 to research on delivery of mental health services, including about $1.8 million that will be used to support five Centers for research on the Organization and Financing of Care for the Severely Mentally Ill. NIMH hopes to increase its services research activities still further and in ways that will generate important research findings to assist Federal, State, and local authorities in making more cost effective use of mental health resources.

As part of its new priority on treatment and services research, the Institute is developing a Public-Academic Liaison program to increase foster increased research cooperation between public mental health service systems and academic research programs. Further information on this initiative will be contained in a special NIMH announcement to be released later this year.

Question. What are the needs for mental health services research? What has research shown to be the most appropriate and effective care for persons with various kinds of serious and persistent mental disorders?

Answer. There is a critical need for research that will examine the rapidly changing mental health service system, evaluate major innovations in the provision of mental health services, examine the role of economic factors in mental health service delivery, and point the way toward development of more cost-effective patterns of service delivery that also meet acceptable standards of quality of care. Research is particularly important on: (1) clinical issues such as diagnosis, treatment, and continuity of care, (2) systems levels studies that clarify effective ways of organizing comprehensive systems of care, especially for the severely mentally ill, and the best ways to pay for needed care, and (3) issues related to provision of improved mental health services to children and adolescents, the elderly, minority group persons, and rural populations.

Recent NIMH research has demonstrated that the most appropriate and effective form of care for persons with serious and persistent mental disorders is often a combination of pharmacological and psychotherapeutic treatment in conjunction with a range of support services. Equally essential for successful treatment and recovery is the effective coordination and continuity of these various components of care. NIMH services research initiatives, in conjunction with other NIMH initiatives such as the 1988 NIMH National Plan for Schizophrenia Research, are placing increased emphasis on generating new research findings that can facilitate the effective transposition of proven treatments into mental health service delivery systems.

Question. Which patients do best in hospitals? What is the optimal length of stay? What accounts for the wide variations in length of stay in hospitals in differing parts of the country?

Answer. There is currently no consensus on which types of patients do best in mental hospitals or on what optimal lengths of stay should be. The success of a treatment plan is dependent upon diagnosis and the severity of the illness. One factor that was pointed out in the development of Diagnostic Related Groups (DRGs) for Medicare was that diagnosis was not a predictor of length of stay or use of resources for mental illness. Quite often the variation in length of stay is contingent upon the financing mechanisms and resources available in that locale.

Some of the relevant issues are being addressed by research in private psychiatric hospitals, such as the Menninger Foundation, where work is being done to develop improved measures of optimal treatment and length of stay. But the applicability of these efforts to patients in state mental hospitals is unclear. The area is clearly one which requires greater research attention, but this is hampered by the absence to date of adequate and readily accessible data on treatment needs of mental hospital patients and the efficacy of treatments that are being applied. Data on variations in length of state mental hospital stay have only recently begun to be available and appear to reflect the wide variations that exist in many parts of the country with respect to availability of community alternatives to hospitalization. The NIMH expects in future to devote more research attention to issues related to regional and other sources of variation in length of stay. In addition, as part of the priority that it is now giving to treatment and services research, the NIMH plans to support research that can help to identify optimal types of hospital treatment that are also cost-effective.

Question. How good is the research on community care? Does it work? Is it cost effective? What are the best studies? Are they adequate? What research is planned for FY 1989?

Answer. Much good research exists on community care for persons with serious and persistent mental disorders. A recent review identified 14 experimental studies that randomly assigned patients to alternative models of community care and hospital treatment: the review found the alternatives generally were more effective and less costly than hospitalization across a wide range of patients and treatment strategies. Among the better studies of community care are those of the "Training in Community Living Model" first used in Madison Wisconsin and replicated in Sydney, Australia, and those of the Fountain House, Thresholds, Soteria, and Fairweather Lodge programs. Research that NIMH is currently planning to support in FY 1989 includes an evaluation of the effectiveness of alternative community treatments for homeless mentally ill persons, the effectiveness of a new capitation payment system in establishing efficient community systems of treatment for severely mentally ill persons, and the effectiveness of four types of innovative city-wide treatment programs for severely mentally ill persons.

Question. Professor John Talbott is quoted as saying that there is a major gap in our ability to define criteria which match optimal treatments to patient needs.

"What specific treatments and care elements work for which patients in what settings (e.g., medication, psychotherapy, vocational and social rehabilitation, and case management), including their cost versus benefit, treatment and program effectiveness, and quality of life determinations."

Is this true? What research is needed, is ongoing, or is planned to address this need in FY 1989? Is it due to a lack of funds?

Answer. An important need in the area of clinical mental health services research is to collect data that can improve our abilities to match patients and their families with specific types of needed mental health treatments (e.g., medication, family intervention, day treatment, case management, brief hospitalization) and evaluate related cost-effectiveness and patient outcomes. The relative absence to date of studies addressing these issues is a reflection of the complex research issues in this area — and the difficulty of developing relevant and well-designed studies. The NIMH plans to place increased emphasis in FY 1989 and future years in developing research in this area as part of its new priority on treatment and services research.

Question. We have heard about the private sector initiatives — the Robert Wood Johnson Foundation — Housing and Urban Development Department Program for the Chronically Mentally Ill and the Robert Wood Johnson Foundation's Program for Services Development for the Chronically Mentally Ill. These programs will provide over $42 million of private funds and over $75 million of HUD funds for demonstrations.

These demonstrations appear to provide unique opportunities for mental health services research. What funds has NIMH committed to do research on these demonstrations in FY 1988 and FY 1989?

Answer. The NIMH will commit $70,000 in FY 1988 and the same amount in FY 1989 as part of its contribution to the Federal share of the $4 million evaluation study of the demonstration projects that have been implemented in nine U.S. cities under the Program for the Chronically Mentally Ill. The evaluation is jointly funded by the Robert Wood Johnson Foundation and is being conducted under the direction of Howard Goldman, M.D., Department of Psychiatry, University of Maryland at Baltimore. The NIMH also plans to commit approximately $215,000 in FY 1988 and a similar amount in FY 1989 to support a mental health services research project that is taking advantage of important research opportunities created in Denver by the Robert Wood Johnson Foundation demonstration in that city. (R01 MH42029, "Effectiveness of Innovative Treatment for the Chronically Mentally Ill," David L. Shern, Ph.D.).

Question. How does NIMH plan to take advantage of these unique opportunities?

Answer. NIMH staff have worked actively to encourage and assist the development of additional research proposals to capitalize on the important opportunities for mental health services research that have been created by the Robert Wood Johnson Foundation demonstrations. Technical assistance has been provided to over two dozen potential applicants, with the result that nine new research grant applications pertaining to these demonstrations have been submitted to NIMH.

Question. What funding is needed to capitalize on these opportunities?

Answer. The amount of funds needed to support new research grants pertaining to the Robert Wood Johnson Foundation demonstrations will depend upon the number of applications that pass successfully through the usual NIMH review for scientific and technical merit and receive good priority scores.

Question. What funds will be available in FY 1988 to implement the needed research?

Answer. In August 1987, the NIMH announced that it planned to make up to $2,000,000 available in FY 1988 to fund new research grant awards on services for the severely mentally ill. Applications pertaining to the Robert Wood Johnson Foundation demonstrations are eligible to compete for these funds and for additional funds that will become available in FY 1989 and thereafter.

Question. What technical assistance is NIMH providing to the nine RWJ Foundation-HUD cities and to the other 45 cities that applied to participate in the RWJF-HUD demonstrations and to the applicants for the RWJ Foundation Services Demonstration Program? Will the research opportunities that these demonstrations present be utilized? What is the amount of funds currently available for technical assistance concerning research on these demonstrations?

Answer. The NIMH has not been directly involved in providing technical assistance to cities and persons who have applied to the Robert Wood Johnson Foundation for demonstration grants. The NIMH has concentrated its efforts instead on insuring that the best possible use will be made of the research opportunities that these demonstrations present. The NIMH staff have contacted demonstration projects involved in the 9 cities program in order to ascertain willingness to cooperate in NIMH-sponsored research and have used this information in talking to over 25 researchers about possibilities for mental health services studies related to the demonstrations. About 20 investigators have been similarly contacted in order to discuss possibilities for services research projects generated by the services demonstration program. The NIMH plans to continue these efforts until sufficient research studies have been generated or the opportunities created by the demonstrations have passed. The NIMH has made use of available staff time to provide such assistance rather than set aside special funds for this purpose.

Question. How much did the NIMH award in FY 1986 and FY 1987 for research grants concerning the delivery of mental health services to the chronically mentally ill? What was the number of grants amounts, title and location?

Answer. The NIMH awarded $1,660,117 in FY 1986 and $1,893,844 in FY 1987 for research grants concerning delivery of mental health services to the chronically mentally ill. Individual grants are listed below:

RO1 MH40053 FY 86: $348,641
"Capitation Payments System for Chronically
Mentally Ill Patients"
Babigian, Haroutun M., M.D.
Department of Psychiatry
University of Rochester Medical Center
300 Crittenden Blvd.
Rochester, N.Y. 14642

RO1 MH39617 FY 86: $363,981
"Service Needs of the Homeless Mentally Ill" 87: $167,783
Breakey, William Raymond, M.D.
Department of Psychiatry and Behavioral Sciences
Johns Hopkins University
600 N. Wolfe Street
Baltimore, MD 21205

RO1 MH40032 FY 86: $223,228
"Chronic Patients: Effect of Rehabilitation 87: $312,295
on Life Course"
De Sisto, Michael, Ph.D.
Department of Mental Health/Mental Retardation
Augusta, Maine 04333

RO1 MH39092 FY 86: $97,944
"Community Alternatives for Psychiatric
Recidivists"
Dincin, Jerry, Ph.D.
Thresholds
2700 North Lakeview
Chicago, Illinois 60614

R01 MH40314 FY 86: $160,467
"Income Maintenance, Dependence, and Service 87: $261,068
System Use"
Estroff, Sue
School of Medicine
University of North Carolina
Box 3, Wing D 208H
Chapel Hill, North Carolina 27514

R01 MH37051 FY 86: $131,345
"Assessing Client Support and Representation
Services"
Freddolino, Paul P., Ph.D.
School of Social Work
Michigan State University
East Lansing, MI 48824

R01 MH38887 FY 86: $113,992
"Assessing the Effectiveness of Local 87: $106,471
Mental Health Delivery Systems"
Grusky, Oscar, Ph.D.
Department of Sociology
University of California
Los Angeles, CA 90024

R01 MH38772 FY 86: $82,519
"Psychiatric Emergencies - Severity and Quality"
Johnson, Sandra W.
New England Council for EMS
81 Winthrop Street
Augusta, ME 04330

R01 MH41441 FY 86: $138,000
"Reintegrating the Mentally Handicapped" 87: $229,651
Segal, Steven P., Ph.D.
School of Social Welfare
University of California
Berkeley, CA 94720

R01 MH43029 FY 87: $268,061
"Treatment Outcome Study"
Shern, David L., Ph.D.
Division of Mental Health
Department of Institutions
3520 West Oxford Avenue
Denver, CO 80236

P50 MH43703 FY 87: $548,515
"Center on Organization and Financing of Care for
the Severely Mentally Ill"
Steinwachs, Donald M., Ph.D.
Health Services Research and Development Center
School of Hygiene and Public Health
The Johns Hopkins University
624 North Broadway
Baltimore, MD 21205

Question. Was this amount adequate?

Answer. The sums awarded in FY 1987 and FY 1988 were adequate to support all research applications pertaining to the severely mentally ill that had passed successfully through rigorous NIMH review for scientific and technical merit and that were approved for funding with good priority scores.

Question. What amount will be awarded in FY 1988?

Answer. The NIMH plans to award $3.4 million in FY 1988 for research on services to the chronically mentally ill.

Question. What is planned for FY 1989?

Answer. To date, NIMH has received over 50 grant applications in response to its August 1987 announcement which invited research grant applications for research on delivery of services to the severely mentally ill. If approved with good priority scores, these applications will be eligible for initial funding in FY 1988 or FY 1989. The NIMH will continue to encourage increased research on services to the severely mentally ill through reissuance of its current announcement in this area and increased emphasis on the need for studies that (a) address clinical services research issues, and (b) involve cooperation between public sector mental health service settings, both hospital and community, and academic research departments.

Question. What amount is needed?

Answer. We are hopeful that available funds will permit NIMH to maintain and possibly increase its current level of support for research on services to the severely mentally ill. The research needs in this area are immense, and there is an opportunity for the NIMH to generate important new findings through an expanded services research effort linked to the new NIMH National Plan for Schizophrenia Research and the developing NIMH initiative aimed at fostering improved collaboration between public sector mental health services systems and academic research departments.

## HOMELESS MENTALLY ILL

Question. How many of the homeless mentally ill are elderly?

Answer. Very little information is available on the proportion of the homeless mentally ill population that is elderly. Elderly persons comprise a very small subgroup of the general homeless population. A National Institute of Mental Health (NIMH)-sponsored study of the homeless population in Ohio found that 6.4 percent of the homeless in shelters, streets, and other unacceptable living arrangements were 60 years of age or older, as compared to 22 percent of the general population.

An NIMH-sponsored study of the homeless in New York City determined that 4.4 percent of shelter users were 60 years or older. Elderly homeless persons were less likely than younger homeless persons to suffer from mental illness (13.7 percent versus 20.2 percent). Elderly homeless persons were also less likely than younger homeless persons to have been hospitalized during their lifetime for psychiatric problems (15.1 percent versus 22.3 percent). These figures are rough estimates since they were based on informal shelter intake procedures, rather than formal diagnostic screening. It is likely that among elderly homeless persons, dementias and other cognitive impairments are more common forms of mental disability than among younger homeless persons.

Question. What is the status of research concerning the mentally ill homeless?

Answer. Most research on the homeless mentally ill population to date has been descriptive and cross-sectional in nature. The National Institute of Mental Health (NIMH) funded 10 pioneering and rigorous research studies on the characteristics and service needs of the population. Nine of these studies were conducted in local geographic areas, and one (Ohio) used a Statewide sample. The NIMH convened three annual meetings in 1984, 1985, and 1986 to enable the researchers to compare their findings, discuss methodological barriers to studying the population, and distill implications of their findings for service delivery and public policy reforms. The NIMH is now preparing a written synthesis of these 10 research studies for dissemination to the field; this report will be available in Summer 1988.

Question. How many research grants were awarded in FY 1986 and FY 1987 concerning the mentally ill homeless? How many will be awarded in FY 1988?

Answer. NIMH awarded ten research grants between FY 1983 and FY 1985, for local studies of the characteristics and service needs of homeless mentally ill persons. One of these grants, which was awarded to the Johns Hopkins University, was still active in FY 1986 and FY 1987.

In FY 1988, NIMH funded two new research awards focused on the population: a one-year supplement to the Baltimore study, and a three-year grant to the University of Missouri at St. Louis for an evaluation of an NIMH-funded demonstration project providing outreach and case management services to homeless mentally ill persons.

Question. What research is needed? What are NIMH's plans for research concerning the mentally ill homeless?

Answer. A multi-phase research and evaluation strategy is needed to continue to build a knowledge base on the homeless mentally ill population and its service needs. The first effort in this strategy is a national evaluation of the Community Mental Health Services Demonstration Projects for Homeless Individuals who are Chronically Mentally Ill, funded under Section 612 of the Stewart B. McKinney Homeless Assistance Act (P.L. 100-77). Focused on nine large-scale comprehensive service system projects for homeless mentally ill adults, the national evaluation will involve a rigorous, systematic analysis of the implementation of each demonstration project. This first evaluation will establish a foundation for future evaluation and research studies, generating hypotheses and research questions and providing information on the conditions, resources, processes, and approaches needed for subsequent outcome studies.

A similar, smaller scale evaluation is planned for the three services demonstration grants for homeless children and adolescents who are either emotionally disturbed or at risk of emotional disturbance. This evaluation will involve an examination of the implementation of the projects and will assist in the development of an outcome evaluation plan.

Other research and evaluation activities are needed to both support and extend these two initial implementation evaluations. In particular, once the services demonstration projects have achieved full implementation, there will be a need for focused, controlled evaluations of their effectiveness and impact. The focus of these evaluations should be both on client outcomes and on the projects' impact on the community service system.

In addition, a "second generation" of research on the homeless mentally ill population is needed. Building on the lessons learned through the ten NIMH-sponsored studies conducted between 1984 and 1986, the research that is required includes:

- o rigorous, epidemiological studies that can provide more reliable estimates of the number of homeless persons with severe mental illness;
- o longitudinal research investigating both the causes of homelessness and the course of homelessness; and
- o focused research on the service needs of subpopulations of the homeless mentally ill (e.g., homeless mentally ill women, families with children who are severely emotionally disturbed).

Question. What barriers exist to getting the research needed for a better understanding of persons who are homeless and mentally ill?

Answer. Research on the homeless mentally ill population is difficult. Due to the very nature of homelessness, methodological and logistical problems are inherent in conducting research on this population. Areas of methodological difficulty experienced by researchers in this area are sampling, instrumentation, longitudinal research, and problems incurred by the lack of consensual definitions of key concepts such as "homelessness", "service systems", and "mental illness".

Many of the methodological barriers, however, can be resolved through a series of sequential research studies. Although NIMH has been successful in stimulating some activity in this area through the sponsorship of ten descriptive research studies and annual researcher meetings, the cadre of researchers is still small and the National Institute of Mental Health (NIMH) research portfolio is narrow in scope. However, longitudinal research grants focused on this population and its service needs, utilization, and outcomes would aid in attracting researchers dedicated to this area. Moreover, opportunities for federal departments and agencies (e.g., Health and Human Services(DHHS)/NIMH, HHS/Office of Human Development Services, Housing and Urban Development, Department of Labor) to jointly support research would stimulate more comprehensive and complex research studies that are responsive to the multiple needs of this heterogeneous population.

## MENTAL HEALTH SERVICES RESEARCH

Question. Centers for research on the organization and financing of care for the severely mentally ill. Why are such centers needed? How many centers are needed?

Answer. Almost 2.5 million Americans are persistently disabled by severe mental illness. The task of insuring that these Americans are provided with effective, humane, and coordinated care is a major social challenge that is being complicated by major changes in systems of care that include cost containment initiatives in the Medicaid and Medicare programs, limits on state and federal budgets, the growth and emergence of strong competitive forces in private systems of mental health care, and the disproportionately large representation of persons with severe mental illness among the medically indigent. These new pressures have exacerbated historical problems associated with fragmentation in sources of public funding for the severely mentally ill and their dependence on multiple public systems for housing, social welfare, rehabilitation, and medical and mental health care. It is increasingly recognized that new approaches to the organization and financing of care are needed, but the acceptability and social implementation of these will depend upon convincing research evidence that new approaches are more effective and efficient than what currently exists.

The Centers for Research on the Organization and Financing of Care for the Severely Mentally Ill were developed by NIMH in 1987-1988 in order to provide more stimulating and productive research environments in which experienced clinical researchers, economists, and sociocultural researchers, could interact and direct their energies toward the conceptualization and implementation of multifaceted research programs on the delivery services to individuals with severe mental disorders. The Centers are emphasizing studies of long-term public sector care for this population and also provide a structure for developing research results to increase the efficiency and effectiveness of service delivery.

The current desire is to fund five of these Centers -- two on the East Coast (Johns Hopkins University, Rutgers University), two on the West Coast (Oregon Health Sciences University, Western Consortium for Public Health), and one in the Midwest (University of Wisconsin) — appears to be a reasonable approach.

Question. Which departments of psychiatry have major programs of mental health services research? How are these research programs funded?

Answer. Among Departments of Psychiatry with strong programs of research in mental health services research are those at the University of Maryland in Baltimore, Johns Hopkins University, the University of Wisconsin-Madison, the University of California-San

Francisco, the University of California-Los Angeles, and Yale University. These programs are funded through Federal grants, foundation grants and departmental funds. We expect that programs of mental health services research in these and other Departments of Psychiatry will further develop and strengthen as a result of new NIMH initiatives that include the planned issuance of a new services research announcement, the 1988 release of the NIMH National Plan for Schizophrenia Research, and increased NIMH emphasis on fostering improved research cooperation between public sector mental health service systems and academic research programs.

Question. The December editorial in Science states that the whole deinstitutionalization of the mentally ill was done without any adequate research and cites only one recent comparative study. Is this an accurate statement of the research? What is being done about it?

Answer. The process commonly referred to as deinstitutionalization (i.e., large scale depopulation of state hospitals) was possible only because of two factors: the introduction in the 1950's of psychotropic drugs that helped to control the symptoms of mental illness, and the broad expansion of community programs in the 1960's that created new opportunities to relocate severely mentally ill persons in the community. Sustained research on the consequences of deinstitutionalization began in the 1970's and led to the publication of several major reports by government and private agencies. The results of this research have also appeared in journals such as Hospital and Community Psychiatry, New Directions in Mental Health Services, and Schizophrenia Bulletin. With the passage of time, research emphasis has shifted away from deinstitutionalization and focused more on the needs of severely mentally ill persons who now live in the community and are hospitalized for only short periods of time. The new priority placed by NIMH on treatment and services research is placing increased emphasis on studies that can assist in the development of improved clinical and other services for this population. At the core of this effort are the NIMH Centers for Research on the Organization and Financing of Care for the Severely Mentally Ill.

## PREVENTION AND TREATMENT OF CRACK ABUSE

Question. Title IV of the Omnibus Anti-Drug Abuse Act of 1988, S. 2205, is our attempt to reduce the demand for the drugs that are undermining the future of too many young Americans.

Subtitle B of Title IV of this Act is designed to expand the Alcohol, Drug Abuse and Mental Health Block Grant and the Substance Abuse Emergency Drug Treatment Programs for fiscal years 1989, 1990, and 1991.

While our bill increases the available budget authority substantially, I am concerned that there are real gaps in our knowledge about drug treatment and prevention methods -- especially as this knowledge base applies to the widely used cocaine derivative, crack. I am confident that our knowledge base is more solid for the substances that have been around longer -- marijuana, hallucinogenic drugs, cocaine, and alcohol abuse.

As we rapidly move forward with our new Omnibus Anti-drug legislation, I would like to be on more solid footing with regard to making workable treatment and prevention programs available for crack addicts — especially those who are in their teens and early twenties.

As I investigate this concern, I am not hearing good news. It seems that very little is known about treating a young addict. The rapid growth of the use of crack confirms my second concern -- we apparently, as a nation, do not know how to prevent young Americans from trying this extremely dangerous and addicting drug.

I would welcome your comments and suggestions for refining S. 2205 to assure our supporters that we are making the best possible use of the anticipated expansions I have described. These programs -- the ADM Block Grant and the emergency drug treatment program -- are the two key Federal sources of local treatment and prevention money.

I am in favor of expanding our treatment and prevention programs, but I would also like to know that we are also expanding our knowledge base for treating crack addicts, enticing crack addicts into treatment, and preventing future relapses.

Please give me your best thinking about ways to establish a crack treatment and prevention program that will at least have some hope of succeeding, especially for the young abuser.

Answer. The "crack" form of cocaine as used by teenagers and young adults has only recently emerged as a major drug problem. Thus, our knowledge of about treatment programs and therapeutic methods that might be effective for these young crack smokers is slowly accruing from ongoing clinical studies that focus on the treatment of adults using cocaine administered primarily through inhalation but also through the intravenous route. Results from these projects, several of which have been conducted at large NIDA supported treatment centers, are very encouraging. That indicate that antidepressant medication can significantly reduce the likelihood of severe depression as well as the strong craving for the stimulant that usually follows withdrawal from cocaine. Further, results from related research indicate that adding an individual psychotherapeutic component to traditional addictions counseling tends to lower both dropout during as well as the rate of relapse following treatment. This finding is especially true for young adult drug abusers entering treatment with high levels of emotional disturbance. In summary, what has been learned from adult treatment studies promises to be helpful in planning treatment for older adolescents who present with similar psychiatric disturbance and drug-abusing profiles.

Although the majority of aforementioned studies focus on the young and middle-aged adult rather than the young drug abuser's response to specific interventions, NIDA is currently supporting a number of treatment studies that take into account the youthful status of the chemically dependent person, whether or not crack is that teenager's drug of choice. Several projects, addressing the needs of both single and polydrug users, target and utilize the powerful influence of parents and older brothers and sisters in either initiating and maintaining or in reducing and eliminating the younger sibling's use of illegal drugs. Thus far most of these studies have successfully employed one of the many variations of family based therapy. In contrast to this heavy emphasis on family pressure, the relatively stronger influence of the peer group on the older teenager forms the basis of the Therapeutic Community model of treatment. The powerful positive aspects of peer group pressure direct and reward the adolescent's efforts to become and remain abstinent.

Even though the results of past and present studies appear to hold promise for effectively treatment adolescents and young adults already using crack, a number of challenging problems remain. These concern the identification of effective methods to engage these youth and their families in the treatment process, the implementation of strategies to retain the adolescents in the prescribed program long enough to obtain maximum benefit, and the provision of aftercare programs and transitional services for those youth that successfully complete treatment. If all concerns could be met through the establishment of comprehensive community treatment systems designed to meet the needs of today's adolescents and young adults, it is reasonable to believe that "treatment" would also be "prevention." To make available appropriate treatment to all members of a high risk family might well prevent their youngest members from escalating and early experimentation to a heavy use of crack cocaine and other highly addicting drugs. To provide effective therapeutic programs and posttreatment services to older adolescents and young adults might well prevent their relapse to drug use.

## HEALTH RESOURCES AND SERVICES ADMINISTRATION

## STATEMENT OF DR. DAVID N. SUNDWALL, ADMINISTRATOR

**ACCOMPANIED BY:**

**DR. JAMES A. WALSH, ASSOCIATE ADMINISTRATOR FOR OPERATIONS AND MANAGEMENT**

**DR. J. JARRETT CLINTON, DIRECTOR, BUREAU OF HEALTH PROFESSIONS**

**DR. ED MARTIN, DIRECTOR, BUREAU OF HEALTH CARE DELIVERY AND ASSISTANCE**

**DR. DANIEL WHITESIDE, DIRECTOR, BUREAU OF MATERNAL AND CHILD HEALTH AND RESOURCES DEVELOPMENT**

**DENNIS WILLIAMS, DEPUTY ASSISTANT SECRETARY FOR BUDGET, OFFICE OF THE SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### OVERVIEW OF HEALTH RESOURCES AND SERVICES ADMINISTRATION

Senator CHILES. Our next witness this morning is Dr. David N. Sundwall, the Administrator of the Health Resources and Services Administration.

The Health Resources and Services Administration administers several programs that address the delivery of health care services to mothers and children and to medically underserved populations. These programs include the maternal and child health block grant, the national health service corps, the community and migrant health centers, and the new infant mortality initiative.

The agency also administers grant and loan programs to educate, train, and place health care professionals. These health professions programs run the entire health care spectrum from pediatrics to geriatrics.

In addition, special emphasis is placed on the training of minority health professions.

Finally, the agency coordinates the development of health resources through programs such as the organ procurement network program and the AIDS health services demonstration program.

Dr. Sundwall, we are interested in talking to you about several issues this morning. We want to know more about the agency's proposal to cut $172 million from the health professions program. We want to hear about the new infant mortality care management program and the medical malpractice data bank.

If you would introduce your colleagues to us and proceed with an oral summary of your testimony.

## INTRODUCTION OF ASSOCIATES

Dr. SUNDWALL. Thank you, Mr. Chairman. We are pleased to be here today.

Before I give my statement, I would like to introduce my colleagues here at the table. To my immediate left is Dr. James A. Walsh. He is the Associate Administrator for Operations and Management.

On his left is Dr. J. Jarrett Clinton. He is the Director of the Bureau of Health Professions.

On my right is Dr. Ed Martin. He is the Director of the Bureau of Health Care Delivery and Assistance.

On his right is Dr. Daniel Whiteside. He is the Director of the Bureau of Maternal and Child Health and Resources Development.

To his right is Mr. Dennis Williams. He is the Deputy Assistant Secretary for Budget of the Office of the Secretary of HHS.

I would like to give a summary of my remarks and then submit a full statement for the record, if that is all right.

Senator CHILES. That will be fine.

Dr. SUNDWALL. As you have just said, the activities of the Health Resources and Services Administration are designed to provide support through grants and contracts for the delivery of health care services for special populations. We work to improve the supply, distribution, and quality of the Nation's health professionals to provide technical assistance, to improve the utilization of health resources and facilities.

The agency's budget request for 1989 for these programs is approximately $1.3 billion, with over 1,500 full-time equivalent positions for program and direct operations. I think it is important for you to understand that in the past year our agency adopted a motto, "Helping Build a Healthier Nation."

This is a fitting and appropriate goal. Our clients in fact are mothers and children, the poor, the medically underserved, migrants, students, persons with AIDS, chronic lung disease and Hansen's disease, and those in need of organ transplantations, the homeless and those who are too sick to leave their home to get medical care.

When we assist any of these people, we feel we are indeed helping build a healthier nation.

Let me just spend a few minutes now to comment on our proposals. First of all, in direct delivery of health care, we are requesting the full authorization level, $400 million, for our community health centers; $43 million for migrant health centers; $3 million for black lung clinics.

In managing these primary care programs, the agency has developed a collaborative arrangement with States and, recognizing that States can and do serve with regard to these medically underserved populations, in 1989 we will have a cooperative agreement with 35 States to coordinate the Federal-State programs to develop the delivery of a comprehensive system of primary care for underserved populations.

I know of your deep personal interest and commitment to reducing infant mortality, and we compliment you on your fine leadership at the National Commission to Prevent Infant Mortality.

I will have an opportunity this Monday to give you more detailed information on what we are doing as a Department, but let me tell you what HRSA is doing specifically in infant mortality.

We are requesting $21 million to continue for another year the infant mortality prevention initiative to expand maternal and infant health services and to reduce infant mortality through community and migrant health centers. This will be accomplished through a case managed system of comprehensive care and will focus on the integration and coordination of appropriate services for the clients' pregnancy and the first year of life.

This amount will remain at the 1988 level of effort to enhance State efforts in infant mortality prevention and other high priority health services. It is part of the Secretary's special initiative in infant mortality.

As you know, Secretary Bowen will be here Monday and will be able to provide more information on the Department's activities in infant mortality reduction.

In our agency, we also have the maternal and child health care block grant, and we are requesting funding that at the full level of authorization for 1989. That is a 6.5-percent increase over the 1988 appropriation.

We estimate that about $30 million is used by the States for hemophilia, genetics, and other projects that may help reduce infant mortality.

Just briefly on the National Health Service Corps, we are requesting $35 million for 1989. That is a reduction of $18 million which is possible because of previous successes of the programs in placing corps members in private practice sites in manpower shortage areas and the declining number of obligated individuals.

Congress recently enacted legislation for loan repayment, and we are requesting $2.2 million for 1989 for national and State loan repayment programs, which will allow us to recruit physicians right in their residencies and then place them in manpower shortage areas in return for some assistance in paying off their loan indebtedness.

Regarding health professionals, we are seeking authority for a new $40 million program which we call the Cooperative Health Professions Initiatives Program. This would replace several categorical health programs.

We believe our proposal is timely in that we have had previous successes in training a broad number of health professionals—doctors, dentists, nurses, and allied health personnel. Our proposed new program will allow us to focus on priority areas identified by States, such as the distribution of primary care personnel, nursing shortages, strengthening geriatric training, and increasing training opportunities for minorities and the disadvantaged.

We are requesting funds to continue our organ transplantation activities. A $4 million request will allow us to continue to fund the national computer registry on organ transplantation and the scientific registry, which will monitor the clinical status of persons who have received an organ transplant, and will also enable us to continue some funding of grants to organ procurement organizations.

Last, just a word about some new initiatives. We are seeking funding authority for the Health Care Quality Improvement Act. That is, we are requesting $2.8 million to fund the first phase of a national data bank on medical malpractice. This will allow us to get information on malpractice judgments and settlements on a national level. These are sanctions taken by medical boards, losses of membership in professional societies, and certain professional review actions taken by health care entities.

This data bank would not only cover physicians and dentists, but due to a recent legislative amendment, would include a range of all health professionals licensed by States.

We are also seeking $15 million to support the health care improvement fund. This will allow us to do some assessments of clinical management, diagnostic practices and procedures, and identify wasteful and costly practices which do not improve the quality of care.

We are also seeking $15 million to provide health care for the homeless. We are seeking $1.5 million for our Office of Rural Health Policy.

Inasmuch as I understand the committee had an opportunity to hear about a broad range of AIDS activities funded by the Public Health Service, I will not go into specific information on our AIDS budget unless you have further questions.

In summary, I would just tell you that I am really looking forward to the next year. We have a broad range of programs, all of them designed to help people in need of care, either in providing services or building resources.

We look forward to working with the committee to meet those needs.

## PREPARED STATEMENT

Now, Mr. Chairman, I would be happy to answer any questions you might have.

[The statement follows:]

## STATEMENT OF DR. DAVID N. SUNDWALL

I am pleased to appear before you today to discuss the fiscal year 1989 budget request for the Health Resources and Services Administration.

The activities of the Health Resources and Services Administration provide grants or support for personal health services for special populations and designated beneficiaries; improve the supply, distribution, and quality of the Nation's health professionals; and provide technical assistance to improve the utilization of health resources and facilities. The agency's fiscal year 1989 budget request for these programs is nearly $1.3 billion and 1,553 full-time-equivalent positions for program and direct operations.

This year, our agency adopted a slogan: "helping build a healthier nation." It is a fitting goal. Our clients are mothers and children, the poor, the medically underserved, migrants, students, persons with AIDS, chronic lung disease, and Hansen's disease, those in need of organ transplants, the homeless and those who are too sick to leave their homes. When we assist any of these people, we are indeed helping build a healthier nation.

Since 1982, when the Health Resources and Services Administration was formed by the merger of the Health Resources Administration and the Health Services Administration, its mission has continued to change, adapting to a rapidly changing environment. While an essential focus remains on ensuring health services to persons who might not otherwise receive care, the agency has developed new and innovative approaches to providing that care, and accepted responsibility for a broader range of new issues to address current public health needs.

### Direct Health Care Services

Our FY 1989 budget requests $400 million for Community Health Centers, $43 million for Migrant Health Centers, and $3 million for Black Lung Clinics. In managing these primary care programs, the agency has developed a State-based strategy that recognizes the role that States can and do serve with regard to resources and revenues needed by the community and migrant health centers. In 1989 we will have cooperative agreements with thirty-five States to coordinate Federal and State efforts in planning, development and delivery of comprehensive primary health care services for areas that lack adequate manpower or have populations lacking access to primary care services.

## Infant Mortality

Nearly $21 million is requested to continue for another year the Infant Mortality Prevention Initiative to expand maternal and infant health services to reduce infant mortality through community and migrant health centers. This will be accomplished through a case-managed, comprehensive approach which will focus on the integration and coordination of appropriate services throughout the clients' pregnancy and first year of life. This amount will maintain our 1988 level of effort to enhance State efforts in infant mortality prevention and other high-priority health services. The request is part of the Secretary's Special Initiative in Infant Mortality. Another aspect is Secretary Bowen's participation in the National Commission to Prevent Infant Mortality. I have served as the Secretary's personal representative to the Commission on occasion and this agency has provided logistical and expert program support as needed.

## Maternal and Child Health

The Maternal and Child Health block grant allocates funds to States to provide a broad range of health services including preventive, primary care and habilitative services to mothers and children. Our 1989 request for $561 million is the maximum amount authorized and is $34 million more than the 1988 appropriation, an increase of 6.5 percent. We estimate that about $30 million is used by the States for hemophilia, genetics and other projects which may help us reduce infant mortality.

## National Health Service Corps

The budget request for the National Health Service Corps is $35 million in 1989. This $18 million decrease from 1988 is possible because of the success of this program in previous years in placing Corps members at private practice sites in manpower shortage areas and the declining number of obligated individuals who must serve in the Corps.

Congress recently enacted legislation which authorizes loan repayments in exchange for service in an underserved area. We are proposing an appropriation of $2.2 million to initiate the new National and State Loan Repayment programs. These programs will recruit physicians in residencies or who are already licensed to serve in health manpower shortage areas which cannot otherwise support a doctor in exchange for repayment of a portion of their loans for medical education. Such individuals are a good deal more certain about their career goals than the students who were obligated under the National Health Service Corps Scholarship program.

## Health Professions

In developing resources needed to provide health care, we are proposing flexible health professions training authorities, so that we can target funds to areas of priority need. This budget requests $40 million to begin a new Cooperative Health Professions Initiatives program to replace the categorical programs which will expire this year. These programs have contributed to an impressive increase in the number of health practitioners, but it is timely for the Federal and State governments to work together in a flexible, targeted approach to health professions training. Support provided through the proposed new authority will focus on areas identified by States as requiring priority consideration, such as improving the supply and distribution of primary care providers, including nurses; strengthening geriatric training in order to provide health care for the expanding elderly population; increasing training opportunities for minorities and the disadvantaged; and strengthening the ability of States and educational institutions to deal with training in emerging health care problems. Our new cooperative initiatives program will give priority to projects which encourage cooperation among health educational entities, maximize non-Federal involvement in problem identification and program planning, and would be funded at a significant level from non-Federal sources. We will strongly encourage applications from States or groups of States.

## Organ Transplantation

The public perception of equity and fairness in the allocation of organs for transplantation has improved, as has the number of available organs, with the establishment of the national Organ Procurement and Transplantation Network. Our 1989 budget request of $4 million will continue support of the network, implement a scientific registry of transplant recipients to track the scientific and clinical status of transplantation, and provide grants to Organ Procurement Organizations.

## New Initiatives

As new problems rise in the health care area, we are often the agency which assumes responsibility to deal with them. Our 1989 budget request includes several initiatives designed to provoke a timely response to significant health issues:

- Under the Health Care Quality Improvement Act of 1986, $2.8 million is requested to fund the first phase of a national data bank for the receipt, storage and dissemination of information on paid malpractice judgments and settlements, sanctions taken by Boards of Medical Examiners, losses of membership in professional societies, and certain professional review actions taken by health care entities. The data bank would cover physicians and dentists and, with respect to malpractice settlements and judgments, other categories of licensed health professionals.

A Health Care Improvement Fund in the amount of $15 million will support assessments of clinical management, diagnostic practices and clinical procedures that identify wasteful and costly practices which do not improve the quality of patient care.

o Our 1989 budget would continue Health Care for the Homeless with $15 million for project grants to local public and private nonprofit entities for delivery of primary health care services, alcohol and substance abuse services and mental health services to an estimated 130,000 homeless men, women and children. Grants will be awarded to applicants demonstrating broad community participation and linkages with other community providers of critical support needs of the homeless such as emergency food and shelter.

o Our Office of Rural Health Policy is asking for $1.5 million to fund 3 or 4 Rural Health Policy/Research Centers. These centers will provide an information base and a policy research capability on a wide range of rural health concerns including access to care, financing systems, alternative delivery systems and occupational health issues.

o Although funded through a different account, our AIDS activities continue to be an important part of the battle to control this dreaded disease. In 1989, this agency is asking for a total of $40 million for AIDS projects:

- $10.8 million to continue and expand service demonstration projects in communities with a high incidence of AIDS;
- $5 million to carry on the pediatric demonstration projects started in 1988;
- $12.9 million to expand the Education and Training Centers set up to instruct health care and related providers in the care, treatment, and support of AIDS sufferers;
- $5.1 million for curriculum development on AIDS in our nation's health professions and nurse training institutions; and
- $6.7 million to provide AIDS orientation, training and education specific to the needs of staff personnel in Federally supported facilities such as community and migrant health centers.

In addition to the new initiatives and continuing programs I have mentioned, the Health Resources and Services Administration has taken a lead role in staffing the Secretary's Task Force on Medical Liability and Malpractice. We have taken the lead on designing innovative service approaches for dealing with AIDS, and have provided leadership for the Intragovernmental Task Force on AIDS Health Care Delivery. We have also increased our attention to issues relating to the health care of the increasing aged population. An agency Committee on Aging-Related Issues was recently formed to review current program efforts and to explore new opportunities in this area. Acting on a FY 1987 supplemental appropriation, our Division of Nursing in collaboration with NIH has awarded three grants and a contract totalling almost half a million dollars for projects relating to nurse shortage and retention problems.

I am looking forward to the coming year as an opportunity and a challenge. Thank you for providing me with the occasion to summarize the 1989 budget request for the Health Resources and Services Administration.

Mr. Chairman and members of the Committee, my associates and I will be pleased to answer any questions you may have on the specifics of this budget request.

## BIOGRAPHY OF DR. DAVID N. SUNDWALL

Dr. David Sundwall is the Administrator of the Health Resources and Services Administration (HRSA) having been appointed in August 1986. He is also an Assistant Surgeon General in the Public Health Service Commissioned Corps.

As the HRSA Administrator he is primarily concerned with providing direct health services to persons who might not otherwise receive care, and also with issues affecting the development of resources needed to provide health care. Dr. Sundwall is committed to the new public health issues such as Acquired Immune Deficiency Syndrome (AIDS), organ transplantation, and medical malpractice, and continues his commitment to resolving problems of the homeless, the medically uninsured, minorities, the aged, the health of mothers and infants, and the training of health professionals to meet current and future needs for services. He is assisted by 2,300 employees at central headquarters and throughout the Public Health Service's 10 regional offices and a nearly $1.5 billion budget.

Dr. Sundwall was born and raised in Utah and received his medical degree from the University of Utah in 1969. He completed his residency training under the Harvard Family Medicine Program after an internship at New England Deaconess Hospital in Boston. He is board certified in internal medicine and family practice.

Prior to becoming HRSA Administrator, Dr. Sundwall served for five years as physician advisor to the majority staff of the U.S. Senate Committee on Labor and Human Resources. He taught medicine at the University of California at San Francisco and the University of Utah, and conducted a private practice in Utah. He also served as a consultant to HRSA's Division of Medicine.

He has been editorial advisor to the Journal of Family Practice and the Family Medicine Teacher and has published articles in various professional journals. He is a member of the American Academy of Family Physicians and other organizations.

He was honored with the "Professional Staffperson of the Year Award" in 1983 by the Washington Council on Medicine and Health and has received various other honors and awards.

## INFANT MORTALITY INITIATIVE

Senator CHILES. Thank you, Doctor.

As you know, I am firmly convinced that preventive health care for pregnant mothers is one of the most effective ways to reduce infant mortality in our Nation.

My own State has had a model screening and intervention program based at the University of Florida, which identifies women who are at high risk for early delivery. These women are taught about proper prenatal care and nutrition and are monitored throughout their pregnancy.

Last year, the committee provided $20,105,000 for a similar program in the infant mortality initiative, to be funded through community and migrant health centers.

What assurances do we have that this money is going to be used for infant mortality programs, as opposed to supplementing ongoing operations of the health centers?

Dr. SUNDWALL. As I understand the allotment process, the money is indeed targeted to infant mortality reduction activities. It has been limited to things which are targeted for the women clients of those clinics, and we estimate that through this additional money we can fund care for approximately 25,000 pregnancies.

Now, there is some latitude as to what they do specifically with the money. They can do outreach and they can hire providers to provide the prenatal and postnatal care for those mothers and children.

Senator CHILES. Is there any way we can monitor to see whether it is an effective—even though we are allowing some latitude and it is going within that latitude, that it is just not sort of dumped into the pile and they continue to just do business as usual?

Dr. SUNDWALL. Let me ask Dr. Martin to respond to that specifically to see how we follow up on how those funds are spent.

Dr. MARTIN. Mr. Chiles, we are making the process of awarding this money an entirely separate grant award activity, separate from the regular grants. There will be a specific grant to the 125 to 175 centers that we anticipate will get the money. The grant application will include an explicit set of additional activities related to case management which we will compare with their regular grant to make sure that they are not duplicative or simply moving things from one set of cost categories to another.

The second assurance is the specific expectation for the information gathered and the specific activities which would be accomplished. We are going to measure those things.

Senator CHILES. They have to report on them and you are going to measure them?

Dr. MARTIN. Precisely; yes, sir.

Senator CHILES. Well, I think that is necessary, and it will be helpful to see that we are getting some change in policy for these new dollars.

Dr. MARTIN. Yes, sir.

Senator CHILES. I am delighted to see the administration has agreed with our funding priorities by requesting $20,957,000 for this initiative in fiscal year 1989. I am wondering if additional initiatives would be helpful.

I am very interested in efforts to recruit and retain in the prenatal and perinatal health professions professionals who deliver essential medical care to this vulnerable population.

What is your reaction to these ideas, having the Federal Government pay one-half of the cost of the malpractice insurance for perinatal health care providers, such as obstetricians, family practitioners, nurse practitioners, nurse-midwives?

The estimated cost of that would be like $12 million for 1,350 providers.

Dr. SUNDWALL. The medical malpractice costs are a problem in some of our community centers, but it is certainly a variable situation depending upon the region of the country.

We have a program going on now for recruitment and retention which is administered through our regional health offices throughout the country. There are 10 such regional offices and we are fully aware of the vigor with which we have got to recruit providers to serve in those communities where malpractice costs are a barrier.

We have been providing some assistance with the costs.

Senator CHILES. Have been?

Dr. SUNDWALL. Indeed, we are already paying for some of those costs through the operating or overhead cost of running those centers.

It is a problem, Senator Chiles, and I cannot say that it is not.

Senator CHILES. Well, it may not be in all sections of the country, but it certainly is in our section. We are seeing midwives that simply cannot buy the insurance and obstetricians dropping out.

Dr. SUNDWALL. I would suggest that if there were funds provided for malpractice, it not be limited just to purchasing the insurance, because sometimes it is the cost of the tail that is the barrier and not the occurrence costs.

Senator CHILES. Well, we would like to get with you and discuss that with you.

Another idea would be increasing the national health service corps loan repayment program to recruit additional perinatal health providers.

Dr. SUNDWALL. We have a limited budget that we are proposing for that activity. I am very pleased that Congress and the administration agree that loan repayment is a good way to get providers in these community health centers.

The funds we request would allow us to recruit 50 to 60 such providers for underserved areas, and I believe that is a better way of doing business than the former scholarship program, which was costly and got us caught up in lots of legal battles.

Senator CHILES. Better than the scholarship program?

Dr. SUNDWALL. Our new loan repayment program is going to be a more efficient way of doing business.

Senator CHILES. Your current request supports 38 health care professionals, I see, with $2.2 million.

Dr. SUNDWALL. I am sorry, you are probably right. This year we anticipate we can with loan repayment get 50 to 60 with the budget that we have. The proposed budget would allow approximately 35 to 40 providers.

Senator CHILES. Another idea would be increasing the capacity for community and migrant health centers to hire additional health professionals.

Dr. SUNDWALL. At our migrant health centers, approximately 70 percent of their clinical work is maternal and child health. That is already a focus and an appropriate one for women at risk of premature death or premature delivery or low birth weight babies.

Senator CHILES. I understand some 25 community health centers are going to close this year and will not be replaced with new ones. How were the closing decisions made?

Dr. SUNDWALL. I am sorry, sir? I did not hear the question.

Senator CHILES. How were the closing decisions made?

Dr. SUNDWALL. I would like Dr. Martin, who is familiar with that process, to answer that.

Dr. MARTIN. Yes, Mr. Chairman. On an annual basis, each of our community and migrant health centers is reviewed in an objective and technical grant review process, which allows for their prior year's performance, their adherence to the rules, their ability to effectively provide stewardship of the funds, and lastly but not least, to carry out specifically the responsibilities associated with the 329 and 330 funding requirements.

That particular review process has resulted in an average, over the last 4 or 5 years, of somewhere between 20 and 30 centers either no longer meeting the fiscal, managerial, or clinical requirements of our program, or no longer requiring Federal support.

We average about 20 to 30 of those centers a year. That process is an objective grant review process which is individually tailored to each different grant.

Senator CHILES. Dr. Sundwall, I recently read that a study published in the New England Journal of Medicine disputes the view that there is going to be a surplus of physicians in the year 2000. I understand that is in sharp disagreement with the 1981 Graduate Medical Education National Advisory Committee prediction that there would be a surplus of 150,000 physicians in the year 2000.

I understand the authors of the new study argue that the shortage is going to occur because doctors will pursue careers other than patient care, such as teaching, administration, and research; and the demand for doctor services will increase.

And they have cited new technological advances, such as genetic engineering, and the increase in the aging population and AIDS patients are going to boost demand.

Have you all had a chance to read those studies, and what is your reaction?

Dr. SUNDWALL. Well, in a nutshell, sir, we believe that their projections of need are overestimated and their projections of demand also are incorrect.

We believe we now or soon will have too many physicians in the aggregate. What we agree with in the article is simply that we do have serious shortages of primary care physicians in certain regions of the country doing primary care, and that the overspecialization of medicine has resulted in a continuing problem with primary care services being unavailable in some regions of the country.

It is hard to estimate the right number of doctors, and I believe any estimate would be debated depending upon a person's point of view. We believe the Federal Government has been extraordinarily successful in increasing the numbers of doctors and nurses and allied health personnel in general.

We do not subscribe to the position of the authors of that article.

Senator CHILES. This year I read dozens of articles about a nursing shortage in the United States, and we see nurses are being recruited from Ireland, South Korea, and the Philippines.

In the fiscal year 1987 supplemental, a million dollars was appropriated to study the nursing shortage and the nurse retention issue. That money was to support a joint project of your agency and the National Center for Nursing Research at NIH.

Do you have any preliminary findings? Are we experiencing a cyclical shortage or a structural shortage?

Dr. SUNDWALL. We are fully aware of the concerns about shortages of nurses, in certain hospital settings primarily. It is a serious problem, and I do not want to diminish the concern about the availability of nurses in certain disciplines.

What we are trying to find out are the reasons for the problem. In conjunction with the activities we do in the Bureau of Health Professions and at the National Center for Nursing Research at NIH, the Secretary has established a National Commission on Nursing to study the nursing shortage.

The Commission is chaired by Dr. Carolyne Davis. It will have a preliminary report available in May of this year and a final report available in December. I think the Commission's recommendations will be very useful for all of us who are trying to determine the Federal roles related to the nursing shortage issue.

Senator CHILES. Well, given the fact that last year we funded $54 million subtotal for nurse training, this year I understand you are proposing consolidating all of that into funding it at $40 million, 40 does not go into 54, or 54 does not go into 40 quite as much under my math.

That does not indicate much about a shortage.

Dr. SUNDWALL. In all due respect, I do not know that the nurse training money would be the answer to the current nursing shortage problems in certain hospitals.

I believe it has an awful lot to do with how the hospitals pay nurses and other labor-management issues. We will still continue to graduate more nurses through the end of this century because of the funding that we have provided.

So we continue to train more and more nurses, but the problem is; are they appropriately paid for services, and are there some labor-management issues that might be better addressed in the hospital sector than in the Federal sector?

Senator CHILES. I read that nursing care, particularly in hospitals, is much more intensive and technologically complex because the patients are more seriously ill now.

Are we not able to address some of the retention issue of highly trained nurses through the advanced degree nursing program that we fund?

Dr. SUNDWALL. Dr. Clinton, could you answer that for me? I think that is an area where we could find some answers.

Senator CHILES. Doctor, if you would hold on just a minute, I will be right back.

[Pause.]

Senator CHILES. Go ahead, doctor.

Dr. CLINTON. Mr. Chairman, I think your observation is correct that there is a need for additionally trained nurses to deal with technological issues in some hospitals. It is for exactly that reason that we have tried to restructure our programs into the proposed cooperative health professions initiatives, so that our funds can be directed toward the issues, the needs, and the problems as seen by local areas rather than having categorical programs.

We are saying, yes, in some areas, particularly inner cities where large hospitals exist; they do have certain requirements for nurse training, and our proposed program would be responsive to their needs.

What we are trying to get away from is the categorical program authority of this-for-this and this-for-that. The program that we are proposing would allow us to respond to advanced nursing education if a local area or a State or a public or a private entity believes that to be its most severe problem.

Senator CHILES. Dr. Sundwall, if the authorizing committee chooses to reauthorize the current categorical grant program, do you think any other medical specialties deserve more Federal attention than others?

Dr. SUNDWALL. We believe that there remain concerns about primary care, family physicians, general internists, pediatricians, and teachers of geriatric medicine and the discipline or geriatric practitioner.

I also think public health is still a problem. As we look at the personnel needs for reaching our objectives for the Nation which we are setting for the year 2000, I have some concerns about an adequate number of public health personnel.

Again, I think we can address those concerns through the proposal that we have before the committee, and we will soon have a legislative proposal up for your consideration.

Senator CHILES. As you know, I support the idea of a medical malpractice data bank, in which information about successful malpractice suits and licensure actions is collected. Then this information could be used to check the background of doctors and other providers before they are issued a State license to practice or are given hospital admitting privileges.

Needless to say, there have been some difficulties in getting this program started. First, many people were concerned about the potential liability to the Government. Has that question been resolved?

Dr. SUNDWALL. Yes, sir; we believe it has. There was an amendment made on the National Health Service Corps reauthorization bill that was signed by the President last December that clarified the lack of any responsibility or risk of the data banker.

Senator CHILES. Second, there is a question of cost. What is the total cost of the project?

Dr. SUNDWALL. Well, we are seeking $2.8 million in the 1989 budget. We recognize that that is the initial capitalization cost, and over a 5-year period the cost may be approximately $13 million. I have heard higher projections but we do not agree with them.

There are some capitalizing costs, but there is also authority to levy a user fee, and we expect that a good part of the costs of the data bank will be met by the participants paying a fee to tap into that information.

Senator CHILES. Well, if the data bank is funded this year, when do you think we could get it operational?

Dr. SUNDWALL. We believe it could be up and running very soon after the enactment of appropriations, in that we have already had a Federal Register announcement of the proposed rulemaking for the data bank. All we would have to do is solicit bids and award a competitive contract, because we do plan on funding a private sector data banker.

Once we have that contract awarded, we could get underway.

Senator CHILES. Your statement mentions a new $15 million program called health care improvement fund. Evidently, this new initiative is to look for wasteful and costly medical and surgical procedures. That program sounds similar to the patient outcomes program that we funded in the 1988 budget at $1.9 million under the National Center for Health Services Research.

Why are we proposing to establish a new program, instead of building onto the program that we started at the national center? And do you have a research plan you can share with us?

Dr. SUNDWALL. Yes; I certainly do not anticipate starting a new program in addition to what is already underway. In fact, to accomplish the goals that we have in this health care improvement fund, we would collaborate with the National Center for Health Services Research. Some of those funds could be used for them to continue the research that they have done studying patient outcomes.

We believe, however, that there is a broader concern about quality assurance. Once we learn what kinds of practices are wasteful or ineffective, we believe that HRSA, which is the focus of health professions education, could go an awful long way to help that information get out to the practicing physicians, students, and residents in training so that we train them in things not to do and hopefully in a more efficient way of practicing medicine.

It would be a cooperative effort, sir.

Senator CHILES. A new National Health Service Corps loan repayment program was authorized last year. I certainly support that. As I understand it, however, there is a serious problem in retaining these health professions workers once their service commitment is over.

What shortfall do we see in fiscal year 1989 in doctors needed in medically underserved areas, and what should we be doing about it?

Dr. SUNDWALL. Dr. Martin, I would like you to respond to that if you would, please.

Dr. MARTIN. Although there are estimates which range between 300 and 500 of the total numbers of physicians which may be lost 1988 to 1989 and an additional 600 to 800 in 1990 to 1991, based just on normal attrition, we are finding that in many areas we are having significant retention rates within the health centers.

We have an active volunteer recruitment program that has, at least as of the last data we have seen, recruited over 140 additional physicians into those areas. Even with that effort, our current estimate nonetheless is that probably there will be a decrease of somewhere around 200 physicians through this fiscal year and an additional 200 or possibly 300 in the next year, just based upon the large number of people who had been in the scholarship program.

Part of the decrease we feel we might be able to make up through active recruitment. However, the physicians are heavily influenced by, of course, which areas we are trying to recruit them to. Some areas are much more attractive.

Even in your own State, Miami is easier to recruit to than some of the rural migrant sites. But those are our current estimates.

Senator CHILES. In a 1987 Institute of Medicine study, academic geriatrics for the year 2000, it was stated that we will need some 2100 physician faculty and 8,000 geriatric specialists to meet the needs of an increasingly aging population.

Yet, last year this committee appropriated $2,872,000 to fund a new geriatric faculty training program. How many faculty fellowships are we supporting with this level of funding in geriatrics?

Dr. SUNDWALL. Dr. Clinton, do you have that data?

Dr. CLINTON. If I may, we would like to provide that for the record.

[The information follows:]

The first geriatric faculty fellowship awards will be made during the summer, 1988. We estimate that 15 grant awards will be made, supporting approximately 45 physicians and 15 dentists.

Dr. CLINTON. I would say in general that the combination of Geriatric Education Center support plus the other investments in geriatrics have trained a great deal of people across all fields. For example, we have over 2,000 people now who have had more than a 40-hour-training program in geriatrics, and a group 10 times greater than that which has come through various programs in the geriatric educational centers.

We have 40 medical schools involved, 20 dental schools involved, and 20 departments of medical social work. We are seeing now, through the combined efforts of not just the faculty development, but the geriatric education centers and nursing programs, a broad investment in geriatrics training.

Dr. SUNDWALL. Sir, I would just like to augment that a little bit. I am kind of pleased with this personally, because I have a long interest in geriatric medicine. This summer for the first time there will be given a new combined examination of certification of geriatric competence.

It is a joint effort by the American Board of Internal Medicine and the American Board of Family Practice. I think thanks in large part go to the efforts of the Bureau of Health Professions and the programs you funded in the past that there are over 5,000 people who have applied to sit for that test.

That means that some of our training must have done something to prepare them to demonstrate their competence in geriatrics.

Senator CHILES. Well, that study also suggests that we should develop some sort of a critical mass within our medical education system to foster wider clinical opportunities, good institutional training, and strong research at designated centers of excellence.

Are we accomplishing this through this program, or are we scattering our resources?

Dr. SUNDWALL. I do not think so. We have actually funded some 32 geriatric education centers, which are complemented with what the Veterans Administration does through their geriatric research and education centers.

There are identified places that are doing a good job. I am certain some have strengths that are greater than others, but the centers of excellence idea is to give even more resources to one-half dozen institutions that are especially qualified.

I believe we are funding places that are doing a fine job right now.

Senator CHILES. The organ procurement and transplantation program has been funded by the Congress since 1986. This is the first time the administration has requested funding, and we are glad to see that has turned around, at least for this program.

Are both the transplant network and the scientific registry up and running?

Dr. SUNDWALL. Yes, sir; they are.

Senator CHILES. And with these in place, are we going to see an end to the tragic sort of national appeals for organ donors?

Dr. SUNDWALL. We certainly hope so. We cannot control individual actions, but I believe there is a growing consensus that when there is the availability of this national computerized network and now some agreement on the criteria for need or urgency of need of a transplant, that when an individual kind of jumps to the front of the line through the media, that essentially bumps somebody else out of the line.

So there is more fairness in the system now.

Senator CHILES. Do all of the organ procurement centers operate under the same guidelines for organ sharing and distribution? And how do you ensure those guidelines are complied with?

Dr. SUNDWALL. It is a complicated process, because both the Health Care Financing Administration, HCFA, and the Health Resources and Services Administration through our Office of Organ Transplantation are required to set some guidelines. We have tried to cooperate on that, to make sure that they are working on the same wavelength in order to be entitled to funding through Medicare and through the end stage renal disease program.

There are regulations through HCFA, and so I believe there is more uniformity.

Senator CHILES. Well, we understand the demand still greatly exceeds the supply. Last year there were 22,000 brain deaths in the United States, but only 4,000 result in organ donations.

Are we educating the public about the need for organ donation?

Dr. SUNDWALL. Yes, sir; through the budget we are seeking we are planning on some public education efforts.

I would compliment some things being done in the private sector, through the American Council on Transplantation, not to mention efforts through the National Kidney Foundation and others.

It is a complementary effort and we have to keep at it.

Senator CHILES. Last year we put in over $6 million for this program, but this year your budget request is about $4 million, 34 percent less than last year. Where are those cuts going to take place?

Dr. SUNDWALL. The cuts would take place in our grants to organ procurement organizations. By the way, those grants were not to create new entities. They were existing programs.

There were some 110 such entities. Now, under HCFA certification regulations there are 70 certified organ procurement organizations. Those grants were designed to bring them together in regional areas so they were not competing and to get them to behave more cooperatively.

I believe we can continue to reach out to the public through the grants we would make to them, but that is where we would take our cuts.

We would not cut the scientific registry nor the national computer network.

Senator CHILES. In a December 1986 study published by the U.S. Conference of Mayors, it showed that in nearly three-fourths of the cities surveyed families composed the largest number of the homeless for whom emergency shelter and other needed services, such as health care, were particularly lacking.

Congress appropriated $46 million in 1987 and $15 million in 1988 to address the primary health needs of this special group of men, women, and children who have fallen through the social safety net.

Is this program reaching the families? I see your budget request continues funding at $15 million, and that is going to support 53 projects. Given the needs of the homeless population, are the grant recipients able to obtain additional funding from other non-Federal sources?

Dr. SUNDWALL. We certainly hope that this is only part of a much bigger picture to take care of the health needs of these homeless individuals. We are reaching families.

We funded in a rather expedient fashion, I might say with some pride, 108 centers or applications with that $46 million when it was made available. We will have another process that will both give supplementary funds to those who successfully competed and fund some new centers this year.

As you see, the President seeks to sustain that in 1989. Communities stress the needs they have and that certainly includes families.

Senator CHILES. Last year the committee provided $9,574,000 for the excellence in minority health education program. This program was established to strengthen and support the health professions schools which have trained a significant number of the Nation's minority health professionals.

How many grant awards do you plan to make and when will those awards be made? And do the program guidelines follow the history and intent of the legislation?

Dr. SUNDWALL. I know that those are under review right now. We expect to make the awards in July, I believe. I am going to ask Dr. Clinton to address that.

Dr. CLINTON. The announcement for those awards has already been on the street, and we would expect to make the awards in July, after review of the competitive proposals that come forward.

If you recall, there was some discussion about who was eligible for funding under this program. At the present time, according to our general counsel, at least 15 schools are eligible for these funds. We could be making 15 grant awards if indeed they all met the criteria and meet the approval of those individuals who review the proposals.

Senator CHILES. Senator Inouye wanted me to ask, how valuable has the pediatric EMS program been?

Dr. SUNDWALL. They have been excellent programs, sir. They are pediatric demonstrations in the emergency care of children who are either injured or suffer acute illnesses. We have been able to fund over the last few years several demonstrations in pediatric emergency care, and they have served a useful purpose.

Senator CHILES. I understand you helped Senator Hatch when this was first——

Dr. SUNDWALL. Well, I am a bit sympathetic with that, given my previous interest in authorizing that legislation before. But they were intended to be demonstration projects and they certainly have been useful.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. I have other questions and perhaps some of the other members do, too, that we will submit.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## COMMUNITY HEALTH CENTERS

Question. For the past several years, appropriated funds that are not required by the NHSC have been transferred to Community Health Centers to offset the cost of private placements of health care providers. Last month, $12.5 million was transferred.

Given the difficulty in getting this money transferred, should we continue this practice? Shouldn't we appropriate this money up front?

Answer. The funds already transferred in FY 1988 from the National Health Service Corps (NHSC) will be used to support the placement of NHSC providers in positions in Community Health Centers and Migrant Health Centers that represent expansions to their staffing and are therefore not already included in grantees' budgets. Given that, the transfer from the NHSC would be an appropriate way to support the federal share of the salary cost of NHSC providers who are placed in expanded capacity positions at Community Health Centers and Migrant Health Centers.

Question. I see that your FY 1989 request is $400 million. I understand that, at this level of funding, you anticipate a shortfall of 300 providers, such as family practitioners, nurse practitioners, and so on.

What do you plan to do about this?

Answer. At an appropriation level of $400 million for FY 1989, there would not be a shortfall of 300 providers. The level of $400 million would permit the maintenance of the current services level of activity.

## PHYSICIAN SHORTAGE

Question. Dr. Sundwall, I recently read that a study published in the New England Journal of Medicine disputes the view that there will be a physician surplus by the year 2000.

As you know, this conclusion is in sharp contrast to the 1981 Graduate Medical Education National Advisory Committee (GMENAC) prediction that there would be a surplus of 150,000 physicians in the year 2000.

The authors argue that a shortage will occur because (1) doctors will pursue careers other than patient care, such as teaching, administration, and research; and (2) the demand for doctors' services will increase. The study cited that new technological advances, such as genetic engineering, and the increases in the aging population and in AIDS patients will all boost demand.

What are your reactions to the study's conclusions?

Answer. We believe that the study (Schwartz, et al.) published in the New England Journal of Medicine reflects projections of need and demand that are overestimated and projections of supply that are underestimated. The study projects that "patient care" physician needs will exceed the supply by 7,000 physicians. The Schwartz study assumes:

- A strong increase in the demand for physician services in all sectors of the health care system;
- An increase of 75 percent in the number of physicians in research, teaching and administration;
- A lower level of patient care provided by residents; and
- Because of productivity differences, a lower level of patient care provided by female physicians.

In making our projections, as reported in the Sixth Report to the President and the Congress on the Status of Health Personnel in the United States, we used the following assumptions:

- Slower growth in the demand for physician services in the future than there has been in the past;
- More cost-conscious behavior and less willingness by insurers and employers to pay for certain services, e.g., second opinions required for elective surgery;
- A more competitive environment existing for physicians;
- A decrease in the utilization of physician services as documented by fewer office visits per physician, since the supply will increase faster than the demand; and
- Moderate increases in the proportion of physicians in nonpatient care activities.

Although the Schwartz study mentions technology, this is not explicitly studied in the article. It is particularly difficult to predict the impact of technology, as some advances may require more physician services while others may make existing procedures obsolete and some new procedures become widely used while others are so specialized that only a small number of patients actually receive the service.

Question. Given that your Agency is projecting an oversupply of doctors in the year 2000, would you change, or increase your health manpower programs to meet this uncertainty in the supply of doctors?

Answer. Large numbers of physicians have been trained in the United States over the past two decades, due in large part to Federal support. Based on data reported in the Sixth Report to the President and the Congress on the Status of Health Personnel in the U.S., the supplies of most health personnel categories are projected to increase up to the year 2000. Therefore, due to these expanding supplies of health professionals nationwide, support for health professions training was viewed as needing to be targeted on specific geographic, educational, and specialty issues. For example, there continues to be a shortage of primary care physicians to meet the needs of the underserved in our society. As of March 31, 1988 the Health Manpower Shortage Area designation program documented 4,139 primary care practitioners needed to remove the 1,931 shortage areas from designation, and an estimated 12.85 million unserved or underserved persons in these primary care shortage areas.

Our proposed change to the health professions programs is contained in our new Cooperative Health Professions Initiatives program. The proposed authority would allow more flexibility in encouraging States and other non-Federal entities to enter into cooperative arrangements to address high priority health professions issues, contributing their own funds to the solution of these problems to the maximum extent feasible.

## HEALTH PROFESSIONS

Question. We are again faced with a major difference between the Administration and the Congress on the funding of health professions. Two years ago, the Administration proposed no funding for health professions and the Congress appropriated $209.9 million. Last year, the Administration requested $30.5 million for selected health professions, and the Congress appropriated $214.2 million.

This year, you are proposing $40 million for a consolidated grant program.

Dr. Sundwall, in view of the uncertainty about a doctor shortage in 12 years, do you think this is good policy to drastically cut these programs?

Answer. We believe that the Schwartz study reflects projections of need and demand that are overestimated and projections of supply that are underestimated, and therefore their projection of a small (7,000) "patient-care" physician shortage is uncertain, at best.

The Administration's proposed funding for the health professions programs reflects both the Administration's priorities in relation to the budget deficit and our estimates of an increasing aggregate supply of most health personnel categories up to the year 2000.

Question. As you know, the authorizations for the health professions programs expire at the end of this fiscal year. If the authorizing Committee chooses to re-authorize the current categorical grant programs, do you think any medical specialties deserve more Federal attention than others?

Answer. The following areas which would receive high priority funding consideration under our proposed new Cooperative Health Professions Initiatives program also would be our priorities for categorical program support:

- Improving the supply and distribution of primary care providers, including family practice, general internal medicine and pediatric physicians;
- enhancing the availability of health personnel in rural or other underserved areas;
- strengthening training of health providers in geriatric care;
- providing assistance to disadvantaged students;
- increasing training of nurse specialists; and
- providing training related to emerging health care problems.

## NURSING SHORTAGE

Question. This past year, I've read dozens of articles about the nursing shortage in the United States. We see where nurses are being recruited from Ireland, South Korea, and the Philippines.

Dr. Sundwall, in the FY 1987 supplemental, $1 million was appropriated to study the nursing shortage and the nurse retention issue. This money was to support a joint project of your Agency and the National Center for Nursing Research at the National Institutes of Health (NIH).

Dr. Sundwall, what are some of your preliminary findings? Are we experiencing a cyclical shortage or a structural shortage?

Answer. The issues concerning the nursing shortage are complex. It is unclear if the problems being expressed are related to "current imbalance" or to "sustained shortage." In brief, while the aggregate number of nurses is at its highest, demand is increasing and there are significant shortages particularly in hospitals and nursing homes.

Several activities are underway or have been accomplished with the FY 1987 supplemental appropriation to study the nursing shortage and nurse retention issue. The National Center for Nursing Research, NIH and the Division of Nursing, HRSA, recently held two major nationally focused invitational workshops to develop strategies and recommendations on shortage issues related to nursing education, practice and research. The workshops were helpful in identifying the issues and gaps in information available. These results have been made available to the Commission on Nursing which the Secretary has established to study the nursing shortage issue and to develop recommendations as to how public and private sectors can work together to address problems and implement solutions regarding the supply of active registered nurses. The Commission's final report is due in December.

In addition, monies from the budget supplemental were used to award three special project grants which address nursing shortage issues. These projects are in their beginning phases thus findings are not available at this time.

In addition to these activities, HRSA recently awarded a contract to undertake a national sample survey of registered nurses to provide an update on nursing supply and distribution.

All of these activities are being undertaken to obtain more information about the nature of the problem and to identify potential solutions.

Question. I've read that nursing care, particularly in hospitals, is much more intensive and technologically complex, because the patients are more seriously ill. Aren't we able to address some of the retention issue of highly trained nurses through the advanced degree nursing programs that we fund?

Answer. As the knowledge base and technology for advanced practice have increased, there has been an increasing realization that baccalaureate preparation may no longer be sufficient for employment in positions that require mastery of complex content, sophisticated tools and use of complicated data bases. The profession, recognizing these changes, has developed master's programs to educate nurses for specialty practice in a number of clinical areas as well as nursing administrators and educators.

One of the strategies which has been suggested for retaining highly qualified nurses in the nursing profession is to offer opportunities for advanced education. Graduate education provides the foundation for continued professional growth. Advanced nurse education programs which receive some support from our programs produce the new leaders, teachers and clinicians with advanced skills.

## MEDICAL MALPRACTICE DATA BANK

Question. As you know, I support the idea of a medical malpractice data bank, in which information about successful malpractice suits and licensure actions is collected. Then, this information can be used to check the background of doctors and other providers before they are issued a State license to practice, or are given hospital admitting privileges.

Needless to say, there have been difficulties in getting this program started.

First, many people were concerned about the potential liability to the government. Has this question been resolved, Dr. Sundwall?

Answer. Public Law 100-177 contained an amendment to the Health Care Quality Improvement Act that addressed the liability issue by providing relief from liability for any person or entity (e.g., the Federal Government, the data bank operator and public and private agencies which have made suitable arrangements with the Secretary) from any civil action with respect to information provided under the law.

Question. Secondly, there is the question of cost. What is the total cost of this project?

Answer. The estimated cost to fund the data bank under contract is $13.1 million separated into three phases over a five-year period. The $2,800,000 requested in the President's Budget, plus $400,000 in prepaid user fees, will fund the first phase of the contract.

Question. The FY 1989 request is $2.8 million. Will the data bank require annual appropriations to cover the cost of operation?

Answer. User fee income should support the majority of the operating costs of the data bank, once the data bank is fully operational.

Question. If the data bank is funded in FY 1989, when do you think it will be operational?

Answer. We anticipate that a contract award will be made early in FY 1989. We estimate that a contractor will need about 6 months following the award of the contract before the data bank becomes operational.

## HEALTH CARE IMPROVEMENT FUND

Question. Your statement mentions a new $15 million program called the Health Care Improvement Fund. Evidently, this new initiative is to look for wasteful and costly medical and surgical procedures.

This new program sounds very similar to the patient outcomes program we funded in the FY 1988 budget - $1.9 million - under the National Center for Health Services Research.

Why are you proposing to establish a new program in HRSA instead of building onto the program we started at the National Center?

Answer. The HRSA initiative will be complementary to quality of care research undertaken by the National Center for Health Services Research and will build on HRSA's past efforts focusing on quality assurance and the delivery of quality health care.

HRSA's initiative will utilize findings from NIH and NCHSR to effect improved practice of medical care. Further, it will strengthen quality assurance and risk management efforts in hospitals and other health care systems to bring greater analytical review of patient care events and outcomes for the furtherance of quality health care.

Finally, the Health Care Improvement Fund will establish mechanisms that enhance the dissemination of information regarding appropriate cost effective clinical practices to physicians, professional societies, medical schools and third party payors.

Question. Do you have a research plan you can share with us?

Answer. At present, a research plan is under development and will be shared with the Committee when completed.

## GERIATRIC TRAINING

Question. In a 1987 Institute of Medicine study, Academic Geriatrics for the Year 2000, the authors state that by the year 2000 we will need 2,100 physician faculty and 8,000 geriatric specialists to meet the needs of an increasingly aging population.

Last year, this Committee appropriated $2,872,000 to fund a new geriatric faculty training program.

How many geriatric faculty fellowships are we supporting with this level of funding?

Answer. The first Geriatric Faculty Fellowship awards will be made during the summer, 1988. We estimate that 15 grant awards will be made, supporting approximately 45 physicians and 15 dentists.

Question. The Institute of Medicine study also suggested that we should develop some sort of "critical mass" within our medical education system to foster wide clinical opportunities, good institutional training, and strong research at designated "center of excellence." Are we accomplishing that through this program, or are we scattering our resources?

Answer. The new Geriatric Faculty Fellowship program is intended to contribute to the development of physicians for academic leadership in geriatric medicine and, thereby, to the development of a "critical mass" of medical faculty. In implementing this grant program, HRSA has held discussions with the National Institute on Aging (NIA) in order to link the faculty fellowships to NIA initiatives which tend to involve a high degree of geriatric research. We view the new fellowship program as complementary to the "centers of excellence" proposed by the Institute of Medicine. It is widely agreed that the development of academic geriatric medicine requires a broad-based effort and that no single approach is likely to yield an ideal solution.

Question. Last year, we also continued funding $9,574,000 to the geriatric education centers. How many health professionals do we train with this funding?

Answer. In FY 1987, 32 Geriatric Education Centers (GECs) supported the training of 1,300 faculty enrollees in formally planned faculty development programs and 14,600 other participants in GEC sponsored continuing education institutes, workshops, and conferences. It is assumed that approximately the same number of health professionals will be trained in FY 1988.

Question. Do we need to increase our efforts to meet the geriatric health manpower needs for the year 2000?

Answer. As discussed in the Personnel for Health Needs of the Elderly through the Year 2000 report, in the not too distant future almost all primary care practitioners will be caring for patients who are 65 years of age and older. They also will be serving many more older persons as the numbers of persons 65 years of age and over grow more rapidly than the rest of the population. As important as it is to strengthen the geriatric content of basic and advanced education programs preparing future health personnel, these efforts will have only limited effect for many years on the services actually available to older persons. Therefore, the sponsors of continuing education and in-service training programs (including professional associations, educational institutions, public agencies and health care institutions) share with health professionals themselves the responsibility for ensuring that increased attention is given to aging issues.

## EXCELLENCE IN MINORITY HEALTH EDUCATION

Question. Last year, this Committee provided $9,574,000 for the Excellence in Minority Health Education program. This program was established to strengthen and support the health professions schools which have trained a significant number of the Nation's minority health professionals.

How many grant awards do you plan to make, and when will the awards be made?

Answer. It is anticipated that from four to fifteen grants will be awarded under the Excellence in Minority Health Education program in July 1988.

Question. Do the program guidelines follow the history and intent of this legislation?

Answer. We believe the program guidelines follow closely to the history and intent of the "Excellence in Minority Health Education and Care Act" with the exception of eligibility requirements.

Our General Counsel has determined that the HRSA Appropriations Language in the FY 1988 Continuing Resolution modified the eligibility criteria for the Centers for Excellence program, i.e., the Appropriations Language provides that any health professions school that awards a graduate degree in health professions and which has a majority enrollment of minority students is eligible to apply and compete for a grant.

## HEALTH CARE IMPROVEMENT FUND

Question. Senator Proxmire and others helped to pass the patient outcomes legislation back in 1986. As I recall, the legislation specifically authorizes the work to be done by the National Center.

Do you know why the program was dropped from the National Center's budget and put in your Agency?

Answer. The HRSA initiative will be complementary to quality of care research undertaken by the National Center for Health Services Research and will build on HRSA's past efforts focusing on quality assurance and the delivery of quality health care. Further, it will strengthen quality assurance and risk management efforts in hospitals and other health care systems to bring greater analytical review of patient care events and outcomes for the furtherance of quality health care.

Question. Can you tell us what experience HRSA has had when it comes to conducting patient outcome studies?

Answer. HRSA has not conducted patient outcome studies, but will be supporting research in, and enhancement of, quality of care assurance for practitioners, health care institutions and medical/dental disciplinary boards. While outcome research is important, prevention is essential.

Question. Will any of the research funding be contracted out?

Answer. HRSA has proposed that the Health Care Quality Improvement Fund utilize both the grant and contract mechanisms.

Question. Do you have a peer review process set up to handle this new initiative?

Answer. HRSA's Bureau of Health Professions, which will administer the Health Care Quality Improvement Fund, has many years of experience with the peer review process and will utilize peer review groups in the grant awards process for this program.

## RURAL HEALTH POLICY

Question. The Office of Rural Health Policy was created in 1987 to coordinate rural health activities with the Agency and Department. Last year, $1,436,000 was appropriated to fund a small number of rural health policy/research centers. These centers are to develop a policy analysis capacity on the full range of health issues.

Dr. Sundwall, how many grants will be awarded and when will they be awarded?

Answer. We expect to award 3 to 5 rural research center grants in August or early September of this year.

Question. Many rural health policy issues deal with the Medicare reimbursement system. Does your Agency work closely with the Health Care Financing Administration (HCFA) and with the Prospective Payment Assessment Commission (ProPAC)?

Answer. We have developed strong working relationships with both HCFA and the ProPAC. We are reviewing all HCFA regulations and legislative proposals that impact on small rural hospitals and other rural providers. A formal memorandum of understanding between the Office of Rural Health Policy and HCFA has been drafted and will be signed in the near future. The Office of Rural Health Policy is also working closely with ProPAC staff on studies and recommendations that relate to rural hospitals.

Question. What issues, other than the Medicare-related cost issues, will these research centers study?

Answer. The research centers will not focus exclusively on Medicare payment issues. They will address a wide range of issues concerned with improving access to quality care in rural areas, the viability of rural health care delivery systems, and the impact of current health policies on rural health care.

Question. You have requested $1.5 million for this program in FY 1989. Will these awards be new awards or continuations of existing grants?

Answer. The funds requested for FY 1989 will support the continuation of research center grant projects awarded in FY 1988.

## MATERNAL AND CHILD HEALTH (MCH)

Question. The budget request for MCH Block Grant is $561 million, the fully authorized amount. Within that amount, $7.5 million is set-aside for genetic screening.

Will you tell us how many projects that will support, and how these programs help mothers and their infants?

Answer. Although we are estimating 30 newborn sickle cell screening projects with FY 1989 funds, the actual number funded will depend upon several factors, including the number of applications, purpose and objectives, the geographic area and size of population served, the prospective grantee's proposed budget and in-kind contributions. Additionally, we will be providing continued support to those genetic screening projects funded with FY 1988 funds.

The newborn hemoglobinopathy screening program focuses primarily on screening for sickle cell disease because other hemoglobinopathies generally do not lend themselves to techniques currently used in newborn screening. These projects are also concerned with the development of comprehensive clinical management systems for the newborn identified to have significant sickle cell disease including parental education to decrease morbidity and mortality of the disease and to provide genetic counseling.

Question. Do these programs receive other sources of funding?

Answer. A number of these projects also receive funding from private foundations such as the National Foundation/March of Dimes as well as in kind contributions by the grantee and State Title V Block Grant Funds.

## NATIONAL HEALTH SERVICE CORPS (NHSC) SCHOLARSHIP PROGRAM

Question. The Administration is not proposing any funding for the NHSC Scholarship program. Last year, $2,202,000 was appropriated for this program.

If no funds are appropriated in FY 1989, will any students currently in the program be left without financial support?

Answer. Students were granted multi-year funding in their initial award year to cover their support through graduation from health professions school. We estimate that only three scholars, who had discontinued their training for illness or remedial work, will need funding if they return to school or resume their academic schedule in 1989.

Question. This program has been used to recruit Exceptional Financial Need (EFN) students into the NHSC program. What funding alternatives do these students have if the scholarship program is discontinued?

Answer. When the NHSC Scholarship Program is discontinued, most former EFN Scholarship recipients will have available to them a variety of readily available federally guaranteed commercial loans to complete their health professions education. Upon the completion of their training, the NHSC Loan Repayment Program could then obtain their services for the NHSC by entering into agreements with them to pay up to $20,000 a year toward their health professions education loans for each year of full-time shortage area practice they provided under NHSC auspices.

## NATIONAL HEALTH SERVICE CORPS (NHSC)

Question. Dr. Sundwall, the FY 1988 request for the NHSC is $35 million, a reduction of $17,657,000, or 34 percent, from last year's appropriation of $52,657,000.

Will you please explain the cut in funding?

Answer. The $35 million budget request for FY 1989 will provide Federal aid for a NHSC field strength of approximately 2,052 practitioners, serving more than 2.3 million people. The request reflects the funds needed to pay, train, transport and otherwise support the NHSC field staff. In recent years, the program has experienced success in placing large numbers of NHSC obligors in private practice or private placement assignments, as opposed to their direct employment and support by the Federal Government.

Question. Do you anticipate that funding requirements for this program will continue to decrease in future years? Please explain.

Answer. Yes, we are in the process of phasing down the Federal NHSC field staff in favor of State field staffs. We will continue to support recruitment of health care providers through the State loan repayment program.

Question. On page 65 of the budget justification, you mention that $4,140,000 of this funding will be available for cooperative agreements with States. What benefits do these cooperative agreements provide to the program?

Answer. Recipients of NHSC State Contracts or Cooperative Agreements provide the following services:

A central manpower clearing house for recruitment of primary health care providers for underserved areas in the State will be established and/or maintained. Information from the clearinghouse shall be incorporated into the database for the national recruitment clearinghouse administered by the NHSC.

The State agency will: 1) assist in the identification of appropriate practice locations for obligated scholars and non-obligated health professionals; 2) provide a critical link between the NHSC, sites and providers; and 3) participate in site identification and development and recruitment through their manpower clearinghouse function. The State should work closely with the State Primary Care Association (PCA), and with other State and local organizations, in a full range of State-based systems development activities including rural consortia; urban expansion, network development; sponsorship restructuring and manpower development and utilization.

In identifying appropriate practice locations, the State agency will work with the State PCA to identify and develop community-based systems of care in the areas and for the populations of greatest need in the State. These systems will meet the specific needs of those communities and populations. The States will provide a critical link among the NHSC, sites and providers by: 1) working with sites to prepare them for their own role in the recruitment of obligated scholars and non-obligated health professionals; 2) completing matches; 3) notifying regional offices of matches; and 4) submitting match paperwork correctly and on time.

Manpower resources shall be shifted to underserved areas and populations, such as through targeting State Scholarship recipients to serve those with highest need. Through the manpower clearinghouse the State will work with the State PCA and the NHSC to meet the needs of high need areas and populations within the States, by identifying strategies for shifting manpower resources available through State Scholarship or loan forgiveness programs.

Services that assist in the retention and recruitment of providers, such as continuing professional education (CPE), locum tenens, medical school faculty and teaching appointments, coordinated residency training programs, are also made available. The networks established through cooperative agreements and contracts will serve as the foundation for shifting NHSC recruitment administration from the Federal government to the States.

## PODIATRIC MEDICAL EDUCATION

Question. For the past few years, this Subcommittee has called special attention to the shortage of podiatrists in this country. Our main concern has been that the elderly are especially vulnerable to foot problems. Unless they have access to foot care, many of our senior citizens simply cannot get around.

How does this budget you propose get at that problem?

Answer. HRSA is concerned about the foot care needs of the elderly and all citizens. At this point, however, the level of need for podiatric services in the future has not been established through the collection and analysis of pertinent, current data. HRSA is proposing to work with the National Center for Health Statistics to collect the needed data from specific questions to be included in the 1990 National Health Interview Survey, to analyze the data received from this survey and to publish the results in 1991.

The proposed Cooperative Health Professions Initiatives program would provide the flexibility to support high priority health professions needs of the States as they arise.

Question. There are only seven podiatry schools in this country. Specifically, how does your budget proposal help the other 43 States ensure that there is an adequate supply of podiatrists?

Answer. The proposed Cooperative Health Professions Initiatives program would provide the flexible authority needed to support high priority health professions training needs. The high priority training needs of the States should be determined in consultation with the States and other non-Federal institutions and agencies that are most familiar with local and regional personnel needs and available training resources.

Question. What have you done along these lines?

Answer. In addition to the information to be collected in the 1990 National Health Interview Survey, the Podiatric Medicine Training Grant Program has supported the initiation of clinical training in areas having shortages of podiatric manpower as a means of promoting the location of graduates in such areas. It is too early to assess the results of this initiative which started in 1984.

In response to the concerns expressed by the Committee, HRSA is planning to award a two-year contract in FY 1988 to develop and implement faculty development training of selected faculty from the seven colleges of podiatric medicine and from podiatric medicine residency training programs. It is hoped that the outcome of the contract will serve as a stimulant for further development by the podiatric profession.

Question. A few weeks ago, the Senate passed legislation (S. 1968) that would include podiatry in your new geriatric training program.

Given the special needs of the elderly, do you support this legislation?

Answer. We believe that the authority for training of health professions personnel to meet the special needs of the elderly should be a broad, flexible authority permitting the Federal Government to work together with States and other entities in using limited resources available for health professions initiatives in the areas of greatest need. Within the Administration's proposed Cooperative Health Professions Initiatives authority, we would emphasize activities to strengthen training of a range of health providers in geriatric care. One of the advantages of the proposed comprehensive authority would be that it would allow adaptation to changing health care requirements, including those related to care of the elderly, without the need for technical amendments such as those proposed in the Senate passed bill S. 1968.

## PROGRAM MANAGEMENT

Question. The FY 1989 request for staff requirements is a reduction of $4,736,000 and 183 full-time equivalents (FTEs) positions from the current FY 1988 estimate.

In fact, for the past three years, the Agency has reduced staffing by 1,020 FTEs, or 20 percent of the Agency's ceiling.

If the Congress continues to fund the health professions programs, as it has in the past, what would be more realistic funding and staffing levels?

Answer. Approximately $94,221,000 will be required for Program Management to support 1,343 FTEs if Congress continues to fund the Health Professions programs at the FY 1988 level. Of this amount, $70,560,000 is required for salaries and benefits for 1,343 FTEs, $7,668,000 is needed for operating expenses and $15,993,000 is for PHS and Departmental overhead such as the Working Capital Fund.

Question. Has the Agency met a critical point below which staffing cuts should not take place?

Answer. The staff needed depends upon the tasks we are required to perform, staff productivity and use of improved information technology. All of these factors can and will change over time. In FY 1988, HRSA has reached its critical point as staff continues to decline in the face of added responsibilities for infant mortality, loan repayment, health care for the homeless, new AIDS initiatives, rural health and health care improvement functions.

## HEALTH EDUCATION ASSISTANCE LOANS (HEAL)

Question. Have the student loan delinquency rates improved beyond the 1986 figures reported in the February, 1988

General Accounting Office (GAO) report? For the record, would you provide the latest figures for student loan delinquency rates.

Answer. The default and/or delinquency rates for the Health Education Assistance Loan (HEAL) and Health Professions and Nursing Student Loan (NSL) programs in 1986 and 1987 follow:

| HEAL: | 1986 | 1987 |
|---|---|---|
| Dollar Default Rate 1/ | 9.3% | 6.8% |
| Dollar Claims Rate 2/ | 9.6% | 8.0% |
| Dollar Delinquency Rate | 10.8% | 8.3% |
| HPSL Dollar Delinquency Rate 3/ | 2.54% | 2.64% |
| NSL Dollar Delinquency Rate 3/ | 8.68% | 6.27% |

1/ Excludes death and disability claims.
2/ Includes death and disability claims.
3/ The rates shown reflect delinquency for more than 120 days, which is the formula basis required by statute. The rates contained in the GAO report reflected delinquency for more than 60 days.

Question. Do you project that the Student Loan Insurance Fund (SLIF) will remain solvent in FY 1989?

Answer. There are a number of variables involved in making such a determination. Over the past year a rapidly expanding number of loans coming into repayment has resulted in a significant increase in claims for repayment submitted to the SLIF, even though the default rate has not changed. Concurrently, a decline in loan disbursements, caused by the increased attractiveness and expanded borrowing limits of the Department of Education's Guaranteed Student Loans as well as the imposition of a needs requirement on HEAL, has reduced income to the fund. Consequently, the income is not keeping up with the claims and it appears that in FY 1989, for the first time, it will be necessary for the Department to seek an appropriation for the SLIF.

Question. What are your projected default rates in FY 1989?

Answer. We project a 10 percent claims rate against loans coming into repayment in FY 1989.

Question. How does that compare with the Inspector General's estimates?

Answer. The Inspector General in March 1985 projected the HEAL claims rate would reach 15 percent in fiscal year 1987.

Question. In last year's report, the Committee directed the Agency to provide sufficient funds to hire personnel to establish a financial analysis function for the HEAL program. In the Agency's January, 1988 report to this Committee, you state "...the Agency is in the process of acquiring the expertise needed for efficient management of the HEAL program in the areas of financial and market analysis."

Have the necessary staff been hired? What amount of funding is required to hire this staff?

Answer. Specifically, the HRSA is now able to fulfill the following objectives:

1. Provide an end of year report on the HEAL program.
2. Provide to schools on a semi-annual basis a list of their students in default on HEAL loans.
3. Provide the Office of Management and Budget (OMB) with various management reports on a quarterly basis.
4. Develop and produce a monthly internal report on the Student Loan Insurance Fund (SLIF).
5. Utilize in-house capabilities to project the status and trends of the insurance fund.

The HRSA was able to transfer personnel resources into the Division of Fiscal Services to help strengthen the Agency's debt collection activities. These personnel will assure continuous in-house review of the adequacy of program operations and provide the expertise needed for the efficient management of the HEAL program in the areas of financial and market analysis and debt collections activities.

HEAL regulations have recently been implemented which require HEAL lenders to perform many debt collection activities in conformance with the Debt Collection Act of 1982. This Agency has instituted a new procedure whereby upon payment of lender claims for repayment of defaulted loans under the HEAL guarantee, all claims are referred immediately to a collection agency and/or the Department of Justice for collection or adjudication. This procedure reduces the need for an extensive onboard collection staff.

## INFANT MORTALITY INITIATIVE

Question. I'm firmly convinced that preventive health care for pregnant mothers is one of the most effective methods to reduce infant mortality in our Nation. My own State has had a model screening and intervention program, based at the University of Florida, which identifies women who are at high risk for early delivery. These women are taught about proper prenatal care and nutrition, and are monitored throughout their pregnancy.

Last year, this Committee provided $20,105,000 for a similar program, the infant mortality initiative, to be funded through the community and migrant health centers.

Dr. Sundwall, what assurances do we have that this money will truly be used for an infant mortality program, as opposed to supplementing the on-going operations of the community health centers?

Answer. The process of awarding this money is an entirely separate grant award activity from the regular grants to Community Health Centers and Migrant Health Centers. There will be specific grant awards to the 125 to 175 centers that are anticipated to qualify for the funds. The grant application will describe an explicit set of additional activities related to case management which will be compared with the center's regular grant application and progress reports to ensure that the applicant is not duplicating functions or moving ongoing activities from one cost category to another. Following the grant awards, all grantees will be monitored to ascertain their specific activities and accomplishments compared to the expectations of their applications.

## NATIONAL HEALTH SERVICE CORPS (NHSC) - LOAN REPAYMENT PROGRAM

Question. A new NHSC loan repayment program was authorized last year. In return for a minimum two year service commitment in a medically underserved area, a health professional will receive up to $20,000 a year to repay his or her medical education loans. This sounds like a good idea to me.

The FY 1989 budget request of $2.2 million proposes to support 38 health professionals through this program.

As I understand it, however, there is a serious problem of retaining these health professionals once their service commitment is over.

Dr. Sundwall, what shortfall will we see in FY 1989 in doctors needed in medically underserved areas, and what should we do about it?

Answer. Our estimates are that between 300 and 500 of the total number of NHSC physicians will leave in 1988 and 1989 and an additional 600 to 800 in 1990 and 1991, based on normal attrition of scholarship obligors. However, in many areas we are having significant retention within the health centers. We have an active volunteer recruitment program that has, as of the most recent data, recruited over 140 additional physicians into those areas. Even with that effort, the current estimate nonetheless is that there will probably be a decrease of about 200 physicians through this fiscal year and an additional 200 or possibly 300 in the next year.

Part of the decrease might be made up through active recruitment. However, the physicians are heavily influenced by the areas they are being recruited for. Some areas are much more attractive. Generally speaking, urban areas are easier to recruit for than some of the rural migrant sites, and the Northeast, Northwest and California are more likely to attract recruits than the Southwest, Southeast and Alaska.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### AIDS DEMONSTRATION PROJECTS

Question. Dr. Sundwall, as you know, I am very interested in the AIDS Demonstration Projects designed to develop systems of care that provide a variety of services to people with AIDS and offer an alternative to inpatient hospital care.

Congress has funded these projects since 1986. How many projects have been funded?

Answer. The Health Resources and Services Administration (HRSA) made four Service Demonstration Grants awards in Fiscal Year (FY) 1986 to San Francisco, Los Angeles, New York City, and Miami, the four metropolitan areas with the greatest prevalence of AIDS cases at that time. In FY 1987, nine additional grants were awarded to Washington, D.C., New Jersey, Atlanta, Boston, Ft. Lauderdale, Seattle, San Diego, Palm Beach County (Florida), and Orange County (California). In FY 1988, we anticipate that five or six new Service Demonstration Grants will be awarded.

Question. Does the President's budget request include funds to continue and expand these programs?

Answer. The President's Budget Request for FY 1989 calls for an additional $10,567,000 for Service Demonstration Grants designed to address the needs of all HIV infected groups. In addition the President's FY 1989 Budget proposes $5 million for Pediatric AIDS service demonstration projects.

Question. Do any of the projects include advocacy services?

Answer. All recipients of Service Demonstration Grants provide non-medical support services such as counseling and case management. Many grantees also provide legal services, where appropriate.

Question. Do you think there is a need for such a component?

Answer. The need for advocacy services varies with the structure and complexity of the medical and social services available in each community.

### BUDGET REQUEST

Question. Dr. Sundwall, what was your original budget request to the Department? What was the Department's original budget request to the OMB for HRSA and how does it differ from the request before the Subcommittee?

Answer. HRSA does not submit a budget request directly to the Department. Rather, its request goes to PHS, which modifies it for submission to higher echelons. The following table compares HRSA's original budget submission of $1.5 billion to PHS with the Department's budget request of

$1.2 billion to OMB. The President's Budget Request as it stands now before the Subcommittee is also provided for comparison.

HEALTH RESOURCES AND SERVICES ADMINISTRATION
FY 1989 ($000)

| | HRSA Original Budget Req. to the PHS | Department's Original Budget Req. to OMB | Difference Between HRSA&Dept. Budget Requests | President's Budget |
|---|---|---|---|---|
| Health Care Delivery and Assistance | | | | |
| Community Health Ctrs.. | $ 414,000 | $ 400,000 | $ -14,000 | $ 400,000 |
| Black Lung Clinics..... | 3,519 | 3,400 | -119 | 3,255 |
| Migrant Health......... | 46,989 | 45,400 | -1,589 | 43,466 |
| Infant Mortality....... | — | — | — | 20,957 |
| NHSC................... | 39,827 | 37,804 | -2,023 | 35,000 |
| Hansen's Disease Ctr... | 19,465 | 19,737 | 272 | 18,245 |
| Payment to Hawaii...... | 3,416 | 3,300 | -116 | 3,159 |
| Loan Repayment......... | 18,900 | 10,000 | -8,900 | 2,202 |
| Homeless Health Care... | — | — | — | 15,000 |
| TOTAL, BHCDA........... | 546,116 | 519,641 | -26,475 | 541,284 |
| Health Professions | | | | |
| Consolidated health Student loan program.. | 39,715 | 34,730 | -4,985 | — |
| Guarantee authority.... | (395,000) | (100,000) | (-295,000) | (100,000) |
| Cooperative Hlth Prof Program.............. | 100,000 | 26,300 | -73,700 | 40,000 |
| Health Care Improvement Fund................. | — | — | — | 15,000 |
| Special Priority Init.. | 65,000 | 16,200 | -48,800 | — |
| Health Care Quality Improvement Prog...... | 2,100 | 2,100 | — | 2,800 |
| Assessment of H.P. Prog | 3,000 | — | -3,000 | — |
| TOTAL, BHPr............ | 209,815 | 79,330 | -130,485 | 57,800 |
| Maternal and Child Health and Resources Development | | | | |
| MCH Block Grant........ | 561,000 | 494,000 | -67,000 | 561,000 |
| Health Teach Facilities | 500 | 500 | — | 500 |
| AIDS................... | 64,268 | 35,016 | -29,252 | (40,016) |
| Organ Transplant....... | — | — | — | 4,000 |
| TOTAL, BMCHRD.......... | 625,768 | 529,516 | -96,252 | 565,500 |
| Buildings & Facilities.. | 11,316 | 750 | -10,566 | 400 |
| Program Management...... | 96,826 | 81,918 | -14,908 | 76,573 |
| Rural Health........... | — | — | — | 1,500 |
| SUBTOTAL, HRSA......... | 1,489,841 | 1,211,155 | -278,686 | 1,243,057 |
| Medical Facilities Guar/ Loan Fund.............. | 22,000 | 21,600 | -400 | 21,600 |
| TOTAL, HRSA............ | $1,511,841 | $1,232,755 | $-279,086 | $1,264,657 |

## HEALTH PROFESSIONS

Question. Dr. Sundwall, in addition to my obvious objections to essentially "gutting" Federal funds for health professions training, I want to first ask you a more basic question.

Do you believe the Federal Government should have a role in ensuring availability of health care services by qualified health professionals?

Answer. The Federal Government has the role in the national health care system to provide direction, establish national health policy, and carry out enacted legislative provisions. Over the past 2 decades the Federal Government has provided funds to health professions schools to develop, operate and maintain quality health education programs in educational institutions. When there was a projected shortage of health professionals in the 1960s and 1970s, we provided financial assistance to students to pursue health careers so that we now have adequate supplies of health professionals in most categories.

HRSA is now directing its efforts to ensuring and enhancing the quality of health care. We are proposing to implement the Health Care Quality Improvement Data Bank of medical and dental malpractice settlements, judgments and professional disciplinary actions and the Health Care Improvement Fund which will sponsor research on the efficacy of new medical technologies and treatments. In addition, the new program of Cooperative Health Professions Initiatives will provide targeted assistance to help meet high priority health personnel needs including the education of selected types of health professionals.

Question. Why would you encourage maximizing "non-Federal involvement in the identification of problems and the planning of programs to address Health Professions Needs?"

Answer. In an era of limited Federal resources we have proposed a new legislative authority that will enable us to target these limited resources to areas of greatest need.

The Cooperative Health Professions Initiatives program would allow non-Federal entities increased independence and broadened options in developing health professions programs to meet particular State, local, or regional needs. Needs should be identified primarily by the States and other non-Federal institutions and agencies that are most familiar with local and regional needs and available training resources. We would place heavy reliance on the help of non-Federal groups in the planning of necessary types of aid and expect long-range financial support to come from State and local governments.

Question. What do you mean in your budget documents when you say: "The basic training capacity for health professionals appears to be generally adequate to meet overall national health care requirements?"

Answer. There appears to be adequate capacity in health professions education institutions and programs to train health professionals to meet overall national health care requirements. Even though most health disciplines anticipate declines in the number of graduates at least through the mid-1990s, these declines are expected to have virtually no demonstrable effect on the numbers of persons providing services in these fields through the end of this century.

Question. By what standards are you measuring these requirements?

Answer. Requirements for health care professionals are based on a number of factors, such as population growth and resource utilization patterns. Current projections indicate that the aggregate supply of most professions will be in rough balance with requirements at least through the end of this century.

Question. How do these standards differ from the standards used in the study reported in the New England Journal of Medicine recently? As you know, this report indicates that there will be a shortage of physicians by the year 2000.

Answer. We believe that the study (Schwartz, et al.) published in the New England Journal of Medicine reflects projections of need and demand that are overestimated and projections of supply that are underestimated. The study projects that "patient care" physician needs will exceed the supply by 7,000 physicians. The Schwartz study assumes:

- A strong increase in the demand for physician services in all sectors of the health care system;
- An increase of 75 percent in the number of physicians in research, teaching and administration;
- A lower level of patient care provided by residents; and
- Because of productivity differences, a lower level of patient care provided by female physicians.

In making our projections, as reported in the Sixth Report to the President and the Congress on the Status of Health Personnel in the United States, we used the following assumptions:

- Slower growth in the demand for physician services in the future than there has been in the past;
- More cost-conscious behavior and less willingness by insurers and employers to pay for certain services, e.g., second opinions required for elective surgery;
- A more competitive environment existing for physicians;
- A decrease in the utilization of physician services as documented by fewer office visits per physician, since the supply will increase faster than the demand; and
- Moderate increases in the proportion of physicians in nonpatient care activities.

Although the Schwartz study mentions technology, this is not explicitly studied in the article. It is particularly difficult to predict the impact of technology, as some advances may require more physician services while others may make existing procedures obsolete and some new procedures become widely used while others are so specialized that only a small number of patients actually receive the service.

Question. The Department's own 1986 report on the Status of Health Personnel in the United States stated that areas needing increased production of highly trained Public Health specialists includes nurses with a public/community health orientation, who can identify high risk groups, work with community organizations in prevention programs, and deal with the special needs of the elderly, chronically ill and disadvantaged.

In the face of this report and the highly publicized fact that we are experiencing a severe nursing shortage, how can you eliminate a $54 million nurse training program and replace it with a $40 million initiative to:

- improve the supply and distribution of primary care providers (including physicians, nurses, and other, as appropriate);
- increase the linkage between teaching and service functions in health professions education and practice;
- enhance training opportunities in remote or underserved areas;
- strengthen geriatric training;
- provide educational assistance to disadvantaged students;
- expand and improve training in public health and other aspects of health promotion and disease prevention;
- increase training of nurse specialists; and
- provide training related to AIDS and other emerging health care problems.

Answer. The existing authorities, which expire on September 30, 1988, constrain our ability to adapt Federal assistance in any given year to high priority health needs as identified by the States. The proposed Cooperative Health Professions Initiatives program would provide the flexible authority needed to support high priority health professions training needs. The high priority training needs of the States should be determined in consultation with the States and other non-Federal institutions and agencies that are most familiar with local and regional personnel needs and available training resources. Our proposed program would place heavy reliance on the help of non-Federal groups in the planning of necessary types of aid. We would expect long-range financial support to come from State and local governments and the private sector.

The priorities for funding under the proposed legislation would likely be similar to many of the programs supported under the current legislation, i.e., improving the supply and distribution of primary care providers (including nurses), strengthening training in the care of the elderly, assuring adequate educational opportunities for minorities and disadvantaged, and meeting nursing needs.

Specific attention has been given to the nursing shortage issue. On January 22, 1988, the Secretary announced a new Commission on Nursing to study the issues and to develop recommendations for improved recruitment and retention of registered nurses. This Commission will develop a multi-year plan to help attract young people into the nursing profession and encourage them to stay. Also the Assistant Secretary for Health, in conjunction with the Commission, will prepare a departmental plan to implement the recommendations of the Commission.

## COMMUNITY HEALTH CENTERS (CHC)

Question. Dr. Sundwall, all of the CHCs in my State are telling me they are seeing a dramatic increase in patients with increasingly varied health care problems. In particular, they are seeing an increase in people infected with the AIDS virus, many with full-blown AIDS by the time they arrive at the Center.

While I recognize that $400 million is the authorized level, the Administration has proposed new initiatives before, why hasn't the Administration proposed an increase in CHC funding that would assist the centers in responding to the increase in AIDS patients?

Answer. The role of the Community Health Centers in addressing this special population is to act as the deliverer of primary care services and as the care manager for referral to other services in the community. To this extent, health centers have responded to increased numbers of patients in those AIDS-endemic areas that are designated as Medically Underserved Areas (MUAs).

Question. While I understand the President's AIDS budget proposes $6.2 million to train health personnel in federally supported health facilities, do you believe this is enough?

Answer. The HRSA estimates that the proposed funding will be adequate to provide the intense and highly specialized AIDS training for the 5,000 health professionals targeted under this program.

Question. In your professional judgement, do you believe we should "freeze" CHC basic funding at 1987 levels and not increase the staff and operational funds, as well as AIDS training, to meet the AIDS and non-AIDS demands of the centers?

Answer. CHCs in high HIV incidence areas are already implementing appropriate responses to the increased numbers of HIV infected users. The role of the CHC in addressing this special population is to act as the deliverer of primary care services and as the care manager for referral to other services in the community.

Question. What is your response to the Commission's recommendation that calls for the re-instatement of the NHSC program to enlist an additional 200 primary care physicians in training per year, and provide loan forgiveness to 100 additional practicing primary care physicians per year, to staff facilities in underserved, AIDS-epidemic areas?

Answer. We are currently evaluating the Commission's recommendations with respect to AIDS. However, in general, the Administration proposes expanding the NHSC Loan Repayment Program instead of using the NHSC Scholarship Program to recruit primary care physicians. Scholarship program participants often require 7 or more years before they are available for service and always have the potential of being lost to the NHSC in the interim because they shift to non-primary care specialties or move into biomedical research under National Research Service Awards. The bulk of the primary care physicians obtained through the NHSC Loan Repayment Program, on the other hand, will be available for immediate placement in current systems of health care, including those in underserved, AIDS-endemic areas designated as primary care Health Manpower Shortage Areas.

Question. Dr. Sundwall, again last year, Congress directed the transfer of unobligated NHSC program funds to the CHC program to pay for salaries, benefits, and other expenses. Have any funds been transferred to date?

Answer. The amount of $12,250,000 has been transferred thus far in FY 1988 to provide the federal share of support for NHSC providers in CHCs.

Question. If so, how much? With this transfer, will you have to cut basic funding for the centers due to the cut imposed on the centers in the FY 1988 spending bill? If not, when would you expect such a transfer to occur? And how much would you expect to transfer?

Answer. The $12,250,000 transferred from the NHSC is to be used for direct costs related to the support of NHSC providers in CHCs. The first priority is to support the federal share of the salaries of NHSC providers who will be placed during FY 1988 in positions in CHCs that represent expansions to those grantees' staff. Other uses are to support the federal share of increases in malpractice premium costs and increases in salary that are part of a strategy to retain well-trained providers in CHCs who are completing their obligation period.

## HEALTH EDUCATION ASSISTANCE LOANS (HEAL)

Question. For at least the past three years, you have unsuccessfully sought a reduction in the total amount that would be available for loans under the HEAL program, with the Congress consistently rejecting such a proposal.

Are you again seeking such a change in the loan limitation amount and, if so, how much would you reduce it from the current amount of $305 million?

Answer. The President's FY 1989 Budget includes $100 million for new HEAL loan guarantee authority, which represents a $205 million reduction from the FY 1988 authority of $305 million. In addition to the $100 million in new loan guarantee authority, $76 million in unused loan guarantee authority would be carried over from FY 1988. The new HEAL regulations, which went into effect in January of 1987, added the requirement that borrowers demonstrate financial need to obtain a HEAL loan. The effect of this provision has been to lower the demand for HEAL loans to a level more in line with the President's proposal.

Question. What do you think are your chances of getting congressional approval for such a change in the limitation amount when you have consistently failed to do so in the past?

Answer. New loan guarantee authority has been decreased from the $305 million level in FY 1988 in order to limit Government insured borrowing to meet the most critical student needs, as well as to reduce the Federal Government's out-year liability for loan defaults. Additionally, the loan ceilings for the programs administered by the Department of Education have been increased substantially, making additional resources available to health professions students.

The loan guarantee limitation in Title VII of the PHS Act for FY 1989 would authorize continued support for those students who had received support prior to September 30, 1988. We believe that this level of continuation support is excessive.

### HEAL LOANS/STUDENT LOAN INSURANCE FUND (SLIF)

Question. As I understand it, the SLIF pays for defaults and costs associated with unpaid loans due to death or disability. The SLIF is maintained with monies charged to student borrowers who receive HEAL loans. The current premium charged to the student for this fund is 8 percent.

Do you have plans to increase this premium charged to the students beyond the current 8 percent?

Answer. Proposed legislation is pending in Congress which would eliminate the insurance premium ceiling (currently 8 percent) and would allow the Secretary to affix insurance premiums by discipline, lender, or school as default rates dictate. The President's FY 1989 Budget assumes a 10 percent insurance premium on HEAL loans. An increase of the premium to 10 percent in FY 1989 is necessary in order for the SLIF to retain its solvency; if the premium is not increased, an appropriation of $2.8 million would be required in FY 1989 to cover defaults.

Question. Are default rates increasing or decreasing under the HEAL program over the past few years?

Answer. The dollar default and claims rates decreased from FY 1986 to FY 1987. However, default and claims payments under the HEAL program continue to grow as greater numbers of borrowers enter repayment status. Thus, although the dollar claims rate decreased from 9.6 percent in FY 1986 to 8.0 percent in FY 1987, the claims payments increased from $16.2 million to $20.0 million, as the total loans in repayment status increased from $284.5 million to $578.3 million.

Question. What is the trend?

Answer. The trend over the past few years has been between 8 and 10 percent of loans entering repayment have resulted in claims payments.

Question. For the record, please provide specific figures for student loan delinquency rates.

Answer. The default and/or delinquency rates for the Health Education Assistance Loan (HEAL) program in 1986 and 1987 follow:

| HEAL: | 1986 | 1987 |
|---|---|---|
| Dollar Default Rate 1/ | 9.3% | 6.8% |
| Dollar Claims Rate | 9.6% | 8.0% |
| Dollar Delinquency Rate | 10.8% | 8.3% |

1/ Excludes death and disability claims.

Question. If the delinquency rates are decreasing, why would you seek to increase the SLIF and charge the student borrowers a larger premium?

Answer. The number of borrowers defaulting under HEAL continue to grow as greater numbers of borrowers enter repayment status, though at a decreasing rate of increase. Nearly 10 percent of loans entering repayment have become defaults. These defaults continue to endanger the solvency of the Student Loan Insurance Fund. Continuing action is need to offset this concern.

Question. At the 8 percent premium rate, is the SLIF solvent? If so, why do you need to increase the amount of the fund?

Answer. If the insurance premium remained at the 8 percent level in FY 1989, the Student Loan Insurance Fund would have a negative balance by the end of the fiscal year.

The insurance premium needs to be increased to offset the increased number of claims payments made from the SLIF. Although it is anticipated that the claims rate will remain between 8 and 10 percent, an increasing number of borrowers are entering the repayment system which increases proportionately the dollar amount of claims paid from the SLIF.

## NATIONAL HEALTH SERVICE CORPS (NHSC) SCHOLARSHIPS

Question. The Presidential Commission also recommended that the NHSC Scholarship Program should be reinstated to enlist an additional 200 primary care physicians in training per year, and provide loan forgiveness to 100 additional practicing primary care physicians per year, to staff facilities in underserved, AIDS-endemic areas.

Dr. Sundwall, do you agree that the reinstatement of this program would improve the availability of health care to many poor AIDS patients?

Answer. I believe a better way to meet the urgent need of providing health care to poor AIDS patients would be to use the NHSC Loan Repayment Program. Among the thousands of primary care physicians completing their post-graduate training programs each year, there must be multiplied scores of physicians who would find the NHSC Loan Repayment Program a practical way to relieve the financial burdens of their educational loans in return for 2 to 4 years of professional practice in federally-designated high-need primary care Health Manpower Shortage Areas. This would include providing urgently-needed care for indigent AIDS patients in identified AIDS-endemic areas who are not now being served.

Question. Secondly, how do you explain the Administration's proposal to essentially gut all health professions training for primary care physicians in FY 1989 when the Presidential Commission is proposing ways to increase the numbers of primary care physicians?

Answer. The Administration's proposal for replacing the existing categorical health professions education authorities with a unified comprehensive authority for assistance to States and other entities for projects to meet high priority health personnel needs would not "gut" training for primary care physicians. On the contrary, within the proposed Cooperative Health Professions Initiatives authority, special areas of emphasis would be promoted, which would include focusing of health professions resources to improve the supply and distribution of primary care providers.

## AZT SUPPLEMENTAL

Question. Dr. Sundwall, as you know, Congress appropriated $30 million in the FY 1987 Supplemental Appropriations Bill to help pay for the cost of AZT for those who were medically eligible for the drug but unable to pay for it.

The $30 million was made available through September 30, 1988.

Will all of the money be spent by the end of the fiscal year?

Answer. All States and Territories which received a grant under the program must obligate their funds before September 30, 1988.

Question. Will some of the funds be reallocated among the States?

Answer. These States with a surplus will have their projected remaining allocations redistributed to those with a funding shortage in early Summer 1988.

Question. I understand the reallocation was to take place around April 15th yet I am informed that New York and the District of Columbia have not yet been contacted about how much of their allocation was actually spent.

What assurances can you give me that all of the $30 million will be spent in the next five months?

Answer. State AIDS Drug Reimbursement Program representatives were told that the inquiry for the redistribution of funds would be made during the month of April 1988. On April 25, 1988, the AIDS Drug Reimbursement Program queried the States and Territories, including the District of Columbia and New York State, as to unexpended monies and number of patients served. A response to this inquiry, and tabulation of data, is not expected to be completed until early June 1988. As we've said, those states with a projected surplus will have their funds redistributed to those with a funding shortage.

## DATA BANK

Question. If the National Data Bank for Adverse Information on Physicians and Health Care Practitioners (Clearinghouse) is funded by FY 1989, and the funds are available on October 1, 1988, when do you expect that the award will be made, and when do you expect that the activity will be fully operational?

Answer. We anticipate that a contract award will be made early in FY 1989. We estimate that a contractor will need about 6 months following the award of the contract before the data bank becomes operational.

Question. You have requested approximately $2.8 million in funding for FY 1989. What functions does this cover?

Answer. The $2.8 million, as well as $400,000 in prepaid user fees, will cover design and establishment of the data bank (Phase I). Phase I of the contract work also includes a publicity and educational program to provide technical assistance to participants in the program.

Question. Can the clearinghouse be fully operational with these funds?

Answer. The majority of the operational components will be in place within six months of the contract award but fine tuning will be necessary.

Question. What funding needs do you anticipate for future operational years, 3 to 5 years out?

Answer. Approximately $13.1 million will be required to design, establish and operate the data bank for the first five-year period. We estimate operating costs after the first five years to be approximately $3.25 million annually.

Question. If user fees were imposed in out years, would you still need additional funds?

Answer. No funding other than user fees would be required assuming we prorate to users the full operating costs of the data bank.

Question. Will the funds you have requested be sufficient to cover the clearinghouse and also the requirements of the Fraud and Abuse Act?

Answer. Section 1921 of the Medicare and Medicaid Patient and Program Protection Act of 1987, P.L. 100-93 (Medicare Fraud and Abuse Bill), expands the licensure disciplinary reporting requirements of Title IV of P.L. 99-660 from physicians and dentists to all licensed health care practitioners and health care entities. Although implementation of Section 1921 will bring additional data to and use of the bank, there are limited data to define the costs more specifically. Some additional costs will be incurred in the education of reporting entities of new fields designated in Section 1921 as well as additional costs for development of the system. The user fee should be sufficient to generate the additional funds needed to initially incorporate Section 1921 requirements into Phase I of the data bank contract.

Question. Many States already require some reporting of malpractice payments to State agencies. Since the data bank also requires this reporting, how do you propose to reduce the duplication of efforts? Do you foresee the development of a uniform reporting form?

Answer. There will be some duplication of information sent to State agencies and the data bank, but this is unavoidable. Many States already have their own reporting system in place to record malpractice information. We will reduce duplication where possible.

Question. What efforts will be taken to educate all the entities involved with establishing the data bank and filing reports?

Answer. The scope of work for the data bank contract calls for the design and implementation of a nationwide educational campaign and periodic meetings for those who are required to contribute data to the bank or who are required to query the bank.

## SUBCOMMITTEE RECESS

Senator CHILES. Well, we thank all of our witnesses for appearing.

The subcommittee will now stand in recess until Tuesday, April 26, when we will hear testimony from the National Institutes of Health.

[Whereupon, at 1:15 p.m., Friday, April 22, the subcommittee was recessed, to reconvene at 9:30 a.m., Tuesday, April 26.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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TUESDAY, APRIL 26, 1988

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9:10 a.m., in room SD–124, Dirksen Senate Office Building, Hon. Lawton Chiles, (chairman) presiding.

Present: Senators Chiles and Weicker.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### NATIONAL INSTITUTES OF HEALTH

**STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**ACCOMPANIED BY:**

- **DR. WILLIAM F. RAUB, DEPUTY DIRECTOR, NATIONAL INSTITUTES OF HEALTH**
- **DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES; CHAIRMAN, NATIONAL INSTITUTES OF HEALTH AIDS EXECUTIVE COMMITTEE; ASSOCIATE DIRECTOR FOR AIDS RESEARCH**
- **H. RICHARD MILLER, ASSISTANT DIRECTOR FOR BUDGET, NATIONAL INSTITUTES OF HEALTH**
- **DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, BUDGET, DEPARTMENT OF HEALTH AND HUMAN SERVICES**
- **DR. DONALD A.B. LINDBERG, DIRECTOR, NATIONAL LIBRARY OF MEDICINE**
- **DR. CARL KUPFER, ACTING DIRECTOR, JOHN E. FOGARTY INTERNATIONAL CENTER FOR ADVANCED STUDY IN THE HEALTH SCIENCES**
- **BETTY H. PICKETT, PH.D., DIRECTOR, DIVISION OF RESEARCH RESOURCES**
- **ADA SUE HINSHAW, PH.D., R.N., DIRECTOR, NATIONAL CENTER FOR NURSING RESEARCH**

## OPENING REMARKS

Senator CHILES. Good morning.

Today the subcommittee will begin our review of the fiscal year 1989 budget request for the National Institutes of Health. The request for NIH, including funding for AIDS, is $7.1 billion for 1989. This is $456 million, or 6.9 percent, more than last year.

When I came to the committee in 1973, funding for NIH was $1.8 billion. In 1980 NIH funding was $3.4 billion. NIH has grown over 3½-fold since 1973 and almost doubled since 1980.

When Mr. Natcher, the chairman of our companion subcommittee in the House, came on the committee in 1955, NIH funding was $77 million.

The growth of NIH budgets over the years illustrates our compassion and our commitment to the health and well-being of the people of our Nation and the people of the world.

I think we can all take pride in our achievements in the field of health and medicine. Medical research has made it possible for us to virtually conquer many of the leading killers of a generation ago, including tuberculosis, pneumonia, rheumatic fever, and many others.

In the process we have increased life expectancy by nearly 30 years since the turn of the century, about as much as the gain for the previous 5,000 years. As of now, prolonged and costly illness in later years still robs the elderly of pride, purpose, and their life savings. For them in particular these added years of life that we point to so proudly are often filled with illness, anxiety, and even want.

We have many other challenges ahead. The next major challenge is to add real life to the last years of life for each of our citizens.

In my view our infant mortality rate is still scandalously high, and while we have made tremendous strides in the treatment of cancer, stroke, and heart disease, these major killers still threaten our society.

Of course, foremost on the minds of many is the very real and present threat we face from the deadly AIDS virus. It has already infected over 1.5 million Americans.

Finally, I have been encouraged by NIH advances in neurology and progress being made to understand the human brain, but we still have a long way to go to unravel the mystery of Alzheimer's.

Dr. Wyngaarden, we will take your opening statement. Senator Weicker will be along I suppose momentarily, and we will let him make his statement when he comes.

## NIH BUDGET REQUEST

Dr. WYNGAARDEN. Thank you very much, Mr. Chairman. It is always a pleasure and privilege to appear before you and the committee to present the President's budget request for the National Institutes of Health. We very much appreciate the great interest that you and your committee have shown in the programs of the NIH.

## CENTENNIAL OBSERVANCE

As you know, last year we celebrated our 100th anniversary, and it was a year that was very full—with special events, seminars, symposia, receptions, and events honoring the NIH both in this country and abroad. We think that the year was an unqualified success in meeting the major objectives that were set before us by the Congress; namely, to make the NIH better known to the American people and to present the opportunities in biomedical science in such a way that we would increasingly attract young people on the verge of career decisions.

## THE HEALTH OF BIOMEDICAL RESEARCH INSTITUTIONS

Last fall the Director's Advisory Committee addressed the general topic of the health of medical research institutions because, as you know, well over 80 percent of our budget is spent in grants and contracts to extramural research institutions. The health of the entire biomedical enterprise, therefore, depends very much on the health of these institutions.

We subsequently held meetings in seven cities—San Francisco, Los Angeles, New York, Boston, Dallas, Atlanta, and Chicago—to meet with the scientific community, university officials, and other interested parties and seek their advice concerning present and emerging NIH policies and practices, particularly the peer review system. We received a number of very valuable suggestions that we are now in the process of evaluating and implementing.

## MAGAININS

I would like to call attention to a few of the special research developments of the past year, starting with the discovery of one of our intramural scientists, Dr. Michael Zasloff, of what may turn out to be a new chemical defense system against microorganisms. He observed that surgical wounds in laboratory frogs healed infection-free even though these frogs were put back in tanks that were teaming with infectious organisms. That observation led to the discovery of a new class of proteins from frog skin that appear to be naturally protective substances against a variety of infections. These substances, named magainins, are now under intense study in a number of laboratories at NIH and extramurally.

## RETENTION OF SCIENTISTS

Unfortunately, Dr. Zasloff also illustrated one of our problems; that is, losing talented young scientists. In this case he has left to join the University of Pennsylvania. This highlights some of our difficulties in retaining leading investigators, and it illustrates the widening gap in salaries and other benefits available to senior scientists at the NIH compared with our counterparts in the academic community and in industry.

The OMB has taken note of this developing problem at the NIH and has suggested that we convene an advisory committee through the Institute of Medicine to undertake a 4- to 6-month study to advise on ways in which the environment at NIH might be modified to improve retention and attraction of scientific talent. That IOM committee has been appointed, and its first meeting will be held on May 20.

### HUMAN GENOME

We have recently undertaken a major initiative toward sequencing and mapping the entire human genome. This would have profound implications for understanding some 3,500 or more genetic diseases and would provide an extraordinary repository of information dealing with genetic control of a whole series of life processes that we now understand only vaguely.

In its fiscal year 1988 appropriations, the Congress earmarked $17.3 million for the genome mapping project and an additional $3.8 million for the establishment of a related Biotechnology Information Center at the National Library of Medicine. The President's request for 1989 includes $28 million for gene mapping and $4 million for the information center. Thus, both the Congress and the administration have sent clear messages that they regard this as an important mission of immediate and long-range implications for public health and that mapping of the human genome should begin at once.

An expert committee of the National Academy of Sciences has also urged an immediate beginning to this program, and, on February 29 of this year, NIH assembled an ad hoc program advisory committee of some of the Nation's outstanding leaders in the biomedical sciences to discuss in some detail this whole project of mapping and sequencing the human genome. The committee unanimously endorsed our plan to establish an Office of Research on the Human Genome, headed by an associate director within the Office of the Director of NIH.

We also look forward to establishing an NIH program advisory committee to tap the best minds in related disciplines as this program gets underway and progresses.

### RECENT RESEARCH ACTIVITIES

I would like to mention briefly just a few highlights of recent research activities. A study by the National Institute of Child Health and Human Development has concluded that the drug cysteamine can prevent kidney failure and permit normal growth when given to young children with a rare metabolic disease termed cystinosis. Some of these children have been given this drug for 10 years now, and for the first time we have a treatment for this rare disease that seems to reverse the process and allows the children to grow normally.

Earlier this year the National Heart, Lung, and Blood Institute reported that one of their studies showed that one aspirin tablet taken every other day significantly reduced the incidence of fatal and nonfatal heart attacks in men who had no previous history of heart attacks.

Advances by intramural scientists in the National Institute of Allergy and Infectious Diseases are moving rapidly toward the development of a vaccine against rotaviruses. These viruses are an important source of severe diarrhea, frequently leading to death, particularly in children in third world countries.

Scientists supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases have shown that an immunosuppressive drug, cyclosporin A, is effective in the treatment of psoriasis, a chronic skin disorder. This also bears on the AIDS problem because AIDS patients frequently develop explosive psoriasis.

Finally, a study supported by the National Cancer Institute has shown for the first time an effective regimen for advanced bladder cancer, which affects 50,000 Americans each year. A four-drug combined chemotherapy program has had an overall response rate of 70 percent, with 37 percent of patients having a complete remission. Formerly, this was a very inadequately treated cancer.

## AIDS RESEARCH

AIDS, as you know, remains a very high commitment for research at the NIH. Seventeen of our components are involved in the AIDS program. We recently established an AIDS Program Advisory Committee with membership drawn from outstanding scientists, administrators, and ethicists around the country. The first meeting of that group was held earlier this year.

Another new development in AIDS is an effort to speed the review and award process. That plan is now underway. We expect to shorten considerably the time from receipt of applications to their award.

Intramurally, we recently expanded the bed allocation at the clinical center for additional phase 1 drug studies. Unfortunately, the recruitment of nurses has been slow, so we are not so far along as we would like, but we are continuing to work at that problem.

The first AIDS candidate vaccine began safety testing in the clinical center last October.

Further developments in the area of chemotherapy and AIDS have occurred. AZT is well known to you, but related drugs, such as dideoxycytidine, are also looking promising. An alternate-week therapy of AZT and dideoxycytidine may be equally effective and less toxic.

We have also begun a trial of trimetrexate as an experimental drug in the treatment of pneumocystis carinii pneumonia. It is now available as a treatment investigational new drug.

The 1989 funding request proposes consolidation of funds for AIDS in the Office of the Assistant Secretary for Health. The amount identified for NIH is $587.6 million, representing an increase of $119.8 million, or 26 percent, over the 1988 estimate.

## HIGHLIGHTS OF THE BUDGET REQUEST

Mr. Chairman, the fiscal year 1989 budget request for the National Institutes of Health is $6,535.2 million, an increase of 5.4 percent over the comparable 1988 level of $6,198.9 million. For comparability with 1989, funding for AIDS is excluded from the 1988 total.

The 1989 request would support a total of 20,600 research projects grants, including 5,611 new and competing awards. The average cost increases for these grants would be 4.7 percent for noncompeting awards and 2.9 percent for competing awards.

The 1989 request would support 556 centers, 3 fewer than under the current budget. General clincial research centers would receive a 2-percent increase. The average costs for all other centers would be approximately the same as in 1988.

Research training and research career development activities would remain close to their 1988 operating levels, with an increase of 3 percent for career programs and 2 percent for research training.

The intramural research programs would receive $670.6 million, representing a 3.7-percent increase over the 1988 comparable level. The additional funds would be used to support built-in increases.

Mr. Chairman, this completes my opening statement. I will be pleased to respond to any questions you or members of the committee may wish to ask.

## INTRODUCTION OF ASSOCIATES

I would like to introduce my colleagues at the table, if I may. With me today are Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases, Chairman of the NIH AIDS Executive Committee, and the new Associate Director for AIDS Research at the NIH; Dr. William Raub, Deputy Director; and Mr. Richard Miller, Assistant Director for Budget; and Mr. Dennis Williams from the Department.

## PREPARED STATEMENTS

Senator CHILES. Thank you, Dr. Wyngaarden.

We will insert all the submitted statements from the institute directors in full in the record at this point and then we will go on to some questions.

[The statements follow:]

# STATEMENT OF DR. JAMES B. WYNGAARDEN

Mr. Chairman, it once again is my privilege to appear before you and the members of the Subcommittee to present the President's budget proposal for the National Institutes of Health. Today I will report briefly on some of our activities and plans, and describe the highlights of the request for Fiscal Year 1989. In later statements the Directors of the constituent units of the NIH will present more details about our plans and programs.

It is always a pleasure for us to appear at these hearings because of the depth of information and constructive concern that you, Mr. Chairman, the members of the Subcommittee, and the staff have consistently shown in the programs of the National Institutes of Health. Because of the Subcommittee's interest in the NIH 100th anniversary, I am happy to report the completion of the year's full and varied schedule of centennial observances. It was our objective for the centennial observance that it would help create a better public understanding of the importance of biomedical research. Further, we expected that through the events we might attract the attention of young persons in such a way as to induce them to consider the value and satisfactions of a career in biomedical research. Without going into further detail about the centennial, I am pleased to report that the observance was an unqualified success.

Recently our principal program officials and members of our major advisory groups have been holding hearings in different parts of the nation on "The Health of Biomedical Research Institutions." The meetings have been held in San Francisco, Los Angeles, New York, Boston, Dallas, Atlanta and Chicago. The sessions are attended by members of the scientific community, university officials and other interested parties, whose advice we seek concerning current and emerging NIH policies and practices and any other issues affecting the status of the nation's biomedical research institutions. We consider our working relationships with extramural institutions to be of key importance because the productivity of the nation's medical research enterprise depends in large measure upon the health of the nation's biomedical research institutions.

I am pleased to report two appointments to major NIH positions during the past year. Dr. Katherine Bick had been named our Deputy Director for Extramural Research. Following a successful career in academia, she has served with distinction for 12 years as a scientist-administrator at NIH. The other appointment was that of the first Director of the National Center for Nursing Research, Dr. Ada Sue Hinshaw. She came to NIH from the administration and the faculty of the University of Arizona's Health Sciences Center.

Among the research developments of the past year, I wish to call your attention to one in particular. It was the discovery by Dr. Michael Zasloff, of the National Institute of Child Health and Human Development, of naturally occurring substances that operate as a chemical defense system against microorganisms. While conducting research on an entirely different subject, he made a shrewd observation that surgical wounds on laboratory frogs heal infection-free even when the frog's environment teems with infectious organisms. This led to the discovery of "magainins"--naturally occuring chemicals that protect frogs and possibly humans against infections. Our pleasure in referring to this exciting development is moderated by the fact that Dr. Zasloff will be leaving the NIH intramural programs to join the faculty of the University of Pennsylvania. While many factors usually contribute to such decisions, our ability to retain leading investigators is seriously compromised by the widening gap in the salaries and other benefits available to our senior scientists, as compared with their counterparts in the academic community, and by various Federal administrative requirements.

The Office of Management and Budget has taken note of the Federal administrative controls and procedures, including personnel procedures, space allocation procedures, congressional requirements, and the widening salary gap, that limit the capacity of the NIH intramural research program to sustain its distinguished record of scientific achievement and excellence. If the extraordinary accomplishments of the NIH intramural laboratories are to be assured over the long term, solutions must be found to these administrative barriers.

The Department of Health and Human Services has been encouraged by the Office of Management and Budget to consider a wide range of strategies for assuring the continued scientific excellence of the intramural program, and was advised to ask the Institute of Medicine of the National Academy of Sciences to undertake a study of the options. The study has been commissioned and we expect to have recommendations from the six-month study this fall.

Throughout the scientific community new techniques in the manipulation of DNA and the development of new methods of automated processing of DNA are yielding large volumes of information regarding the human genome. Characterizing the entire human genome will have profound implications for understanding the more than 3500 diseases that are known to involve a genetic defect. This knowledge will enhance our understanding of the normal processes of development by many fold.

Every day brings new information on the location of genes. The locations of new markers, particularly those in close proximity to genes associated with known genetic disorders, are published in each issue of the leading scientific journals. Information on the location of individual genes will become known through the course of scientific inquiry, but if we are ultimately to succeed with this project we must capture information systematically for the construction of the complete map. The staggering volume of molecular data and its cryptic and subtle patterns have led to an absolute requirement for computerized data bases and analytical tools if we are to succeed in this major advance.

In the NIH appropriation for FY 1988 an amount of $17.3 million was earmarked for the genome mapping project, plus an additional $3.8 million for the establishment of a related biotechnical information center at the National Library of Medicine. The President's request for FY 1989 includes $28 million for the mapping and $4 million for the information center. Through the 1988 appropriation and the FY 1989 President's budget, both the Congress and the Administration have sent a clear message that this is an important mission, and that there are immediate and long range implications for public health, and that mapping the genome should begin at once.

An expert committee of the National Academy of Sciences has urged an immediate beginning of a program to discover the location of every gene within human chromosomes, noting that such an effort within the next two decades would greatly enhance progress in gaining new knowledge of human biology and medicine.

While the report was controversial in some aspects, it is sound conceptually. Our 1988 and 1989 efforts signal the beginning of this effort. To coordinate this effort I plan to establish an Office of Research on the Human Genome, headed by an Associate Director within the Office of the Director of NIH. The new office will have a coordination and integration function with regard to our ongoing efforts within all components of NIH. We look forward to the establishment of an NIH Program Advisory Committee on the Human Genome, and for it we intend to tap the best minds in the related disciplines in order to develop a scientific plan and administrative options for promoting rapid progress in methods of mapping and sequencing, and for managing the wealth of information emanating from these studies.

Permit me to mention a few highlights from recent research activities.

- A major study supported by the National Institute of Child Health and Human Development has concluded that the drug cysteamine can prevent kidney failure and permit normal growth when given to very young children who inherit the rare metabolic disease cystinosis. This represents the first effective therapy for any of the genetic disorders known as lysosomal disorders.

- Earlier this year a prevention study, supported by the National Heart, Lung, and Blood Institute, showed that one aspirin tablet taken every other day significantly reduces the incidence of fatal and non-fatal heart attacks in men who had no history of heart attacks.

- Advances made by intramural scientists from the National Institute of Allergy and Infectious Diseases are rapidly moving us toward the development of a vaccine against rotaviruses, the most important cause of severe diarrhea--sometimes leading to death--among young children.

- Scientists supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases have recently discovered that an immunosuppressive drug, cyclosporin A, is highly effective in the treatment of psoriasis, a chronic skin disorder. This discovery--in addition to the evidence showing that a high percentage of HIV-positive patients have symptoms of psoriasis--redirects scientists to look more closely at the possibility that psoriasis is an immune disorder.

- During the past year, studies supported by the National Cancer Institute developed the first highly effective regimen for advanced bladder cancer, a cancer that affects nearly 50,000 Americans each year. In a study of combined chemotherapy using four drugs, there was an overall response rate of 70 percent in advanced bladder cancer, with 37 percent of patients having complete remission.

The NIH has a major research commitment in AIDS. Sixteen NIH components, stressing research in pathogenesis, therapeutics, and vaccine development, are involved. To assist in setting research priorities for AIDS research at NIH, I recently established an AIDS Program Advisory Committee with membership drawn from the country's most distinguished scientists, administrators and ethicists. Another new development in AIDS is our program to speed the review and award of AIDS grant applications. The plan will be announced to the scientific community shortly.

Intramurally, we recently expanded NIH's capacity to conduct clinical research on AIDS patients through a new allocation of beds at the NIH Clinical Center for additional Phase I drug studies. Our intramural and extramural efforts in the areas of drug and vaccine development continue. The first Phase I study of an AIDS candidate vaccine in this country began in October at the NIH Clinical Center, with additional candidate vaccines moving toward testing in our network of Vaccine Evaluation Units.

In the treatment area, various drugs and combinations of drugs are being studied both at the NIH and through the AIDS Clinical Trials Group (ACTG) around the country. One of the most promising treatments being studied is a combination of AZT and a related drug dideoxycytidine, both pioneered as AIDS therapies at the NIH. We also are making use of trimetrexate as an experimental drug for treatment of pneumocystis carinii pneumonia patients who suffer serious adverse reactions to the standard therapy. For this purpose trimetrexate is being distributed under a new FDA procedure as a "treatment investigational new drug" through the National Institute of Allergy and Infectious Diseases. In addition, we have just begun a clinical trial to compare the results from treatment with trimetrexate with the effects of treatment with other drugs. NIH's program to apply techniques of structural biology to the design of new drugs for the treatment of AIDS has begun.

The FY 1989 funding request proposes consolidation of funds for AIDS in the Office of the Assistant Secretary for Health. The amount identified for NIH is $587.6 million, an increase of $119.8 million or 26 percent over the FY 1988 estimate. Detailed descriptions of the AIDS research conducted and supported by the various NIH components are contained within the individual budget justifications and in the PHS consolidated submission.

Mr. Chairman, the FY 1989 budget request for the National Institutes of Health is $6,535.2 million, an increase of 5.4 percent over the comparable FY 1988 level of $6,198.9 million. For comparability with FY 1989, funding for acquired immunodeficiency syndrome (AIDS) is excluded from the FY 1988 total.

The FY 1989 request will support a total of 20,600 research project grants, the largest total number of research grants ever awarded by NIH, 837 more awards than the FY 1988 comparable level. The total number of research project grants, excluding AIDS, is made up of 14,989 noncompeting continuations and 5,611 new and competing renewal awards.

The President's request would allow average cost increases for research project grants of about 4.7 percent for noncompeting awards and 2.9 percent for competing awards.

The FY 1989 request for research centers, $539.2 million, would provide support for 555 centers, three fewer than under the current budget. General clinical research centers would receive a two percent increase. Average costs for all other center grants would be approximately the same as the FY 1988 level.

Research training and career development activities would remain close to their FY 1988 operating levels with an increase of 3 percent for research career programs and a 2 percent increase for research training.

The NIH intramural research program would receive $670.6 million, an increase of 3.7 percent over the FY 1988 comparable level. The additional funds would be used to support built-in increases.

Mr. Chairman, this completes my opening statement, but I will be pleased to respond to any questions you or members of the committee may wish to ask.

## STATEMENT OF DR. DONALD A.B. LINDBERG

Mr. Chairman and distinguished members, the National Library of Medicine is responsible for meeting the information needs of our nation's physicians, research scientists, and other health care professionals as they strive to improve our public health. As a nation, we spend tens of billions of dollars a year on research and treatment of AIDS, cancer, heart disease, and other major human afflictions. Effective biomedical information services are essential to ensure that we maximize the benefits of our enormous investment.

Accordingly, I wish to highlight four programs of the National Library of Medicine which I believe are particularly important: (1) outreach activities; (2) Medical Library Assistance; (3) National Center for Biotechnology Information; and (4) development of a unified medical language system.

### Outreach Activities

The concept of outreach as it applies to NLM's biomedical information services involves two different but related aspects. First, the Library's programs and services must be capable of serving all health professionals, regardless of their geographical location. This has been and continues to be a primary objective of ours. MEDLARS, NLM's family of over twenty different computerized databases, provides online factual data or bibliographic references to a network of thousands of individuals and institutions all across our country at an equal price. The DOCLINE service automatically locates the nearest copy of a needed book or journal within the U.S. Regional Medical Library Network administered by NLM, and then facilitates ordering the required materials.

Second, NLM's information services must be presented to the medical public in order that they have the option to use them. The Congress has recently enacted authorizing legislation directing NLM to devote some of its resources to this challenge. We are undertaking a number of activities in a program to carry out this mandate.

First, we aim to increase the awareness of health professionals of the helpful information services that are available to them. We plan an active program of publications, lectures, demonstrations, and tutorials at scientific meetings. Contract assistance will be sought to help us in exhibiting and demonstrating these information systems at the major medical meetings.

Second, we will step up our training of health professionals to use their own computers to search NLM's many databases. We plan for assistance in this project from Regional Medical Libraries, Resources Libraries, contract assistance, and from automated instructional programs that can be run by health professionals in their own homes and offices.

Third, we have taken steps to eliminate a number of barriers to NLM's online systems by reducing the cost of access by students, by encouraging the use of GRATEFUL MED (both lowering costs and improving access), by extending the systems that electronically route requests for documents, and by keeping in close touch with users through surveys and scientifically designed field evaluation studies. In this way NLM hopes to be in increasingly close contact with individual health care professional users and to benefit from constructive criticism of current systems and suggestions from individual practitioners for even better systems.

Fourth, we have directed special attention to support NIH's efforts to increase availability of scientific information about AIDS. So far, we have been able to design improvements to the currently produced NLM Bibliography on AIDS and to make plans for improvements in AIDS coverage in our computer databases. The latter will involve considerable collaborative work between NLM and the NIAID.

## Medical Library Assistance

Programs authorized by the Medical Library Assistance Act (MLAA)--which is due for reauthorization this year--form the foundation for much of NLM's most useful work. Since the MLAA's passage in 1965, NLM has assisted health science libraries throughout the country to establish, expand or improve their information services. These, of course, benefit directly the health care providers and patients who live in each of the thousands of cities in the United States with participating libraries. These include the seven regional libraries, 125 resource libraries, and over 4,000 basic health sciences libraries in hospitals and health-related institutions at the community level. The RML program has improved access to biomedical information in under-served areas, and performs a major role in the dissemination of the results of biomedical research to health care practitioners. As recommended in the

Board of Regents Long Range Plan, it is critical to retool our nation's medical libraries, so they have available the latest information technologies, equipment, and services to aid health care professionals.

## National Center for Biotechnology Information

Research in biotechnology holds tremendous promise. As genetic secrets are unraveled by our increasingly advanced technological and scientific expertise, we can anticipate that cures to such dreaded diseases as AIDS and cancer will ultimately be realized. However, in biotechnology, more than any other area of the life sciences, the staggering volume of molecular data and its cryptic and subtle patterns created the necessity for computerized databases and analysis tools. The rapid expansion of research data in the field has been accompanied by a proliferation of highly specialized databases, built independently from one another using dissimilar computer systems, incompatible searching methods, and few conceptual linkages between them. With its established expertise in large biomedical databases and the information sciences, the NLM is launching a national program to provide enhanced biotechnology information services to assist researchers in analyzing, recording, and retrieving genetic molecular data more efficiently and effectively.

A new National Center for Biotechnology Information, located at NLM and funded at a level of $3,830,000, was included in the FY 1988 appropriation bill. Currently a major organizational component of the Lister Hill National Center for Biomedical Communications, this Center will eventually emerge as a divisional component of the NLM. The Center concept also includes an extramural research grant initiative for which $1,000,000 has been alloted for FY 1988.

## Unified Medical Language System

A major initiative of the Library, strongly endorsed in the Regents' Long Range Plan, is the development of a Unified Medical Language System (UMLS). The UMLS project seeks to overcome the lack of precise links among related biomedical information in different automated systems. This fundamental problem impedes progress in the entire spectrum of computerized biomedical communications activities. The goal of UMLS is not to impose a single vocabulary on all systems and users, but to make the many disparate classifications of medical knowledge invisible to the user. The UMLS project is both an in-house and contractually supported effort, funded at about $1.5 million per year. The American Medical Association is cooperating in the project by coordinating advice from professional societies and private sector organizations.

While the achievement of the ultimate goal of the UMLS project is far in the future, early steps in the process are yielding immediate payoffs. An example is GRATEFUL MED, NLM's highly successful user friendly software which enables individuals without special training to search MEDLINE and other NLM databases easily and efficiently using a personal computer. In its latest version released this year, GRATEFUL MED assists users in searching NLM databases containing more than 10 million records, and in switching between other programs, such as expert systems, and NLM's databases. Over 8,000 copies of GRATEFUL MED have been purchased by individual health care professionals nationwide through the National Technical Information Service. Another useful byproduct of the UMLS project is MicroMeSH, a microcomputer program for searching and graphic display of NLM's thesaurus MeSH. Developed under contract, MicroMeSH provides students and health professionals an easy way to store and retrieve personal files of pertinent medical information.

## Extramural Programs

The development of a Unified Medical Language System would facilitate progress in two of the Library's extramural initiatives: Integrated Academic Information Management Systems (IAIMS), and research in Medical Informatics. The Library has provided support to approximately a dozen medical organizations for planning and development projects leading to the implementation of institution-wide IAIMS computer networks. These IAIMS would link and relate databases and information files--both within and external to the institution--for improved patient care, research, education, and administration. If fully implemented, IAIMS systems will serve as national models for comprehensive information systems in academic institutional settings.

Medical Informatics is the study of biomedical information, data, and knowledge--their storage, retrieval, and optimal use for problem solving and decision-making. An ultimate goal of Medical Informatics research is the development of specialized computer systems which can help a physician reach the best possible decisions in diagnosing and treating patients. NLM grants support investigator-initiated research and institutional research training to achieve new and more powerful information management tools needed for patient care and research.

## Intramural Programs

The Library Operations division is responsible for NLM's basic mission--to build, maintain, and provide access to the world's largest collection of biomedical literature in support of the progress of medicine and the improvement of public health. In FY 1987 NLM acquired approximately 24,000 books and audiovisual programs, 125,000 serial issues representing 22,000 individual titles and 18,330 modern manuscript items. During the year, the Library cataloged approximately 18,700 books, journals, audiovisual programs and computer software and indexed more than 317,000 journal articles. These bibliographic records were added to MEDLARS--NLM's computerized databases--and published in a variety of catalogs and indexes, including Index Medicus. Last year NLM provided over 4 million online searches to its MEDLARS users.

The Library has the responsibility to preserve the biomedical literature so that it will be available for future generations. To that end, NLM continues to implement the recommendations of the preservation plan adopted in 1985. During FY 1987, the first year of the Library's preservation microfilming contract, 3,960,000 brittle pages were filmed; this rate is expected to increase substantially during FY 1988. As a follow-up to last year's public hearing on the use of permanent paper in the biomedical literature, a task force of publishers, editors, paper manufacturers, and library preservation specialists has been appointed to develop a strategy for increasing the publishers' use of permanent paper.

The Lister Hill National Center for Biomedical Communications, NLM's intramural research organization, explores the use of state-of-the-art computer and communications technologies to improve the acquisition, storage, dissemination, and analysis of biomedical scientific information. Lister Hill Center research projects are focused in areas with long-term potential for improving patterns of information processing, analysis and retrieval on a national scale. These include document image processing, videodisc-based computer assisted instruction and patient simulation, artificial intelligence for medical decision assistance, and natural language processing research.

A primary function of the Toxicology Information Program is to build and make available online, computer files related to toxicology and hazardous chemicals. One of the files available is the Hazardous Substances Data Bank (HSDB) which is a factual, non-bibliographic data bank focusing upon the toxicology of potentially hazardous chemicals. This data bank is built, maintained, reviewed, and updated on NLM's Toxicology Data Network System (TOXNET). HSDB has been an important source of information for emergency response teams conducting clean-up operations of toxic chemical spills in our country and around the world. Information derived from HSDB has helped to guide onsite emergency teams in the safe removal of toxic chemicals.

In summary, the biomedical information programs of the NLM serve as a multiplier, increasing the value of our nation's enormous investment in health research and health care. The more rapidly and efficiently health professionals across the country can exploit the latest knowledge gained from research, the faster we will win the fight against AIDS, cancer, and other dreaded human diseases. Guided by the Board of Regents' Long Range Plan, the NLM directs its resources to meeting this information challenge now and in the future.

Mr. Chairman, the request for the National Library of Medicine for FY 1989 is $70,626,000. I shall be pleased to answer any questions you may have.

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## BIOGRAPHY OF DR. DONALD A.B. LINDBERG

Director, National Library of Medicine

September 21, 1933. New York, New York

Education: A.B., Biology, Amherst College, magna cum laude, 1954; M.D., College of Physicians and Surgeons; Columbia University, 1958.

Professional History: 1984-present, Director, National Library of Medicine; 1971-1984, Director, Information Science Group, University of Missouri School of Medicine; 1969-1984, Professor of Pathology, University of Missouri School of Medicine; 1976-1980, Director, Health Services Research Center with Special Emphasis Health Care Technology Center, University of Missouri-Columbia; 1972-1973, Consultant for Health Sciences to Vice President for Academic Affairs; 1969-1971, Professor and Chairman, Department of Information Science, University of Missouri School of Library and Information Science; 1970-1971, Staff, Vice President for Academic Affairs, University of Missouri; 1967-1970, Director, Regional Medical Program Information Systems; 1968-1970, Staff, Executive Director for Health Affairs, University of Missouri; 1962-1970, Director, Medical Center Computer Program, University of Missouri; 1967-1969, Director, Missouri Regional Automated Electrocardiography System; 1966-1969, Associate Professor of Pathology, University of Missouri School of Medicine; 1963-1966, Assistant Professor of Pathology University of Missouri School of Medicine; 1962-1963, Instructor in Pathology, University of Missouri School of Medicine; 1960-1963, Director, Diagnostic Microbiology Laboratory, University of Missouri Medical Center; 1960-1962, Resident Physician in Pathology, University of Missouri School of Medicine; 1959-1960, Assistant Resident in Pathology, Columbia-Presbyterian Medical Center; 1958-1960, Assistant in Pathology, Columbia University College of Physicians and Surgeons; 1958-1959, Intern in Pathology, Columbia-Presbyterian Medical Center; June 1955-Sept. 1955, June 1954-Sept. 1954, Research Assistant to Dr. O.E. Schotte, Amherst College.

Honors: Phi Beta Kappa; Simpson Fellow of Amherst College (1954-1955); Markle Scholar in Academic Medicine (1964-1969); Sc.D., Amherst College, (Hon. Caus.), 1979; Sc.D., State University of New York, Health Science Center, Syracuse, (Hon. Caus.), (1987).

Professional Memberships: Sigma Xi; American Society of Clinical Pathologists; College of American Pathologists (Telecommunication Network Committee, Committee on Emerging Technology); Missouri State Medical Association; American Association for Advancement of Science; Association for Computing Machines (SIGBIO); Salutis Unitas; American Association for Medical Systems and Informatics, Board of Directors; Symposium on Computer Applications in Medical Care, Board of Directors; National Board of Medical Examiners, Board Member; National Board of Medical Examiners, Executive Board; Washington Society for the History of Medicine; Editor: Information Methods in Medicine, Lecture Notes in Medical Informatics; and Journal of Medical Systems; National Academy of Practice in Medicine Distinguished Practitioner; Computer Science and Engineering Board, National Academy of Sciences (1971-1974); U.S. Representative to International Medical Informatics Association, and Trustee (1975-1984); Institute of Medicine (1985-Present).

# STATEMENT OF DR. CARL KUPFER

Disease knows no national borders. This fact is especially apparent in our current attempts to understand and conquer the growing epidemic of acquired immunodeficiency syndrome, AIDS. Universality of disease becomes more apparent as modern transportation systems make the world smaller. Medical science also knows no national borders. And U.S. scientists are collaborating more than ever with those of other nations to increase our understanding of this disease.

In research against AIDS--and many other diseases--programs of the Fogarty International Center (FIC) help to foster productive scientific relations between U.S. and foreign scientists. Many of the world's most promising postdoctoral scientists conduct research in the United States through FIC fellowships or participate in the NIH Visiting and Guest Researcher programs. Leading U.S. scientists are conducting collaborative research abroad under other FIC programs.

The Senior International Fellowship program provides opportunities for established U.S. biomedical and behavioral researchers to conduct collaborative research in foreign institutions. This scientific interchange is of great benefit to researchers throughout the world in expanding knowledge generally and in studying diseases that occur in the developing world that have an impact on the developed world.

For example, schistosomiasis, a parasitic disease producing inflammation that may cause liver disease, vomiting and death, is a major public health problem, afflicting more than 200 million people in developing nations. Understanding how the immune system responds to and controls the infection is important for the development of a vaccine to prevent the disease. A Senior International Fellow from Brown University collaborated with scientists in England to learn how antibodies in rats resistant to reinfection bound to and immobilized the larvae of the disease's parasites. The knowledge gained from these studies will enhance understanding of host-parasite interactions and will contribute information useful for future vaccine development.

The International Research Fellowship Program continues to do an outstanding job in providing research training opportunities for scientists from other countries who subsequently are able to develop research programs in their home country. Under this program, foreign scientists conduct research on various diseases, disabilities and organ systems in studies that benefit from international collaboration.

My account of the activities of the FIC would not be complete without mentioning the special role we play in fostering health research collaboration internationally, and in coordinating the NIH's cooperative involvement with foreign counterparts. This past fiscal year, the various Institutes were engaged in mutually beneficial research with 80 nations. It is the FIC's responsibility to facilitate this interaction and to ensure that the programs are in consonance with the Administration's foreign policies and objectives.

Two examples will serve to illustrate the focal function of the FIC in this regard: In response to Presidential mandate to give high priority to cooperative activities with India, the FIC staff stimulated NIH's participation in the Reagan-Gandhi Science and Technology Initiative. Currently, we are exploring expansion of the program to a broader range of research topics. It has also led the NIH in utilization of resources available under the Vaccine Action Program recently established by the Health and Medical Science Working Group under ongoing Science and Technology collaboration with India.

Additionally, we have emphasized expanded cooperation with Latin American countries. The FIC has just completed a study of the role of international cooperation in strengthening health research in the Region of the Americas. This was done in our capacity as a World Health Organization Collaborating Center for Research and Training in Biomedicine. This year, we will be working with the other Institutes at the NIH to devise new mechanisms, either regional or bilateral, to identify research opportunities and needs, and to facilitate research that would benefit all concerned. The new U.S.-Brazil science and technology initiative launched in 1986 will allow for some follow-on activity to begin in this area.

The Congress and the Public Health Service have placed top priority on the campaign to curb the spread of AIDS and eventually eliminate it in the United States and throughout the world. The FIC is contributing in significant ways to the NIH and overall PHS efforts to conquer AIDS. International collaboration against AIDS will continue to increase in the years ahead. Research on AIDS, by increasing our knowledge of immune function, will also contribute greatly to progress in other biomedical areas including cancer.

The FIC, on behalf of the NIH and the PHS, was the principal organizer of the Third International Conference on AIDS held in June 1987. The conference included more than 1,000 scientific presentations. More than 7,000 people attended, including over 900 members of the news media. More than any other event since the current epidemic began, this conference attracted world attention to the dangers of AIDS and progress that is being made against this disease. In June 1988, the FIC will provide travel support for investigators to present papers at the Fourth International Conference on AIDS in Stockholm.

An estimated 5 to 10 million persons in more than 130 countries are already infected with the AIDS virus and long-term worldwide research and prevention efforts are vital if we are to stop the spread of this dread disease. In recognition of this, the Congress has provided additional new resources to the FIC. These additional funds will allow the NIH to become more extensively involved in the international aspects of AIDS research. We are coordinating this effort with the NIH Director and various NIH Institutes, including NIAID and NCI, as well as with the World Health Organization. In carrying out our AIDS program, we have a number of priority objectives:

--To strengthen international links for AIDS research, including drug and vaccine development;

--To facilitate cooperation between U.S. and foreign AIDS research scientists; and

--To enhance the research and medical infrastructure in other countries so that all nations--including those in the developing world--can vigorously confront the present and future threat of AIDS.

To accomplish these goals, we have defined four program areas: institutionally based AIDS postdoctoral fellowship programs, enhanced international AIDS research collaboration, expanded training and research in AIDS epidemiology, and support of international components of domestic AIDS research. Projects are being developed in all of these areas. These activities are directed principally to research training that will improve the competency of investigators to conduct AIDS research in their own countries.

Thus, the FIC supports research activities that advance scientific knowledge worldwide, result in improving health of people in the United States, and improve the capability of scientists throughout the world to conduct research independently.

The 1989 budget request for the FIC is $11,338,000, of which $1,852,000 is for core support for the Gorgas Memorial Institute. Mr. Chairman, I will be happy to respond to any questions that you or your colleagues may have.

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## BIOGRAPHY OF DR. CARL KUPFER

Director, National Eye Institute
February 9, 1928. New York, New York.

Education: A.B., Yale University, 1945-48. M.D., The Johns Hopkins Medical School, 1952 Certified. American Board of Ophthalmology, 1958.

Professional History: Internship and Assistant Residency, Wilmer Eye Institute, Johns Hopkins Hospital, 1952-1954. Laboratory Assistant, Biostatistics, Johns Hopkins School of Medicine, 1953-58. Research Fellow in Ophthalmology, Wilmer Eye Institute, Johns Hopkins Hospital, 1957-58. Research Fellow in Ophthalmology, Harvard Medical School, 1958-60. Instructor in Ophthalmology, Harvard Medical School, 1960-62. Assistant Professor of Ophthalmology, Harvard Medical School, 1962-1966. Professor and Chairman in Ophthalmology, University of Washington School of Medicine; Research Affiliate, University of Washington Primate Center, 1966-70.

Professional Organizations: American Physiological Society, Association for Research in Vision and Ophthalmology, American Academy of Ophthalmology, American Ophthalmological Society, Pan American Ophthalmological Society

Honors and Awards: Editorial Board, Investigative Ophthalmology, 1969-1977. Editorial Board, American Journal of Ophthalmology, 1971 to present. Member, Scientific Advisory Committee, Fight for Sight, Inc., 1971 to present. The Secretary's Special Citation, Department of Health, Education, and Welfare, April 1972. The Superior Service Award, Department of Health, Education,and Welfare, May 1974. Ticho Memorial Lecture, September 1974. Migel Medal, American Foundation for the Blind, October 28, 1976. Public Service Award in Ophthalmology, American Academy of Ophthalmology and Otolaryngology, October 1977. Speaker, Glenn A. Fry Award Lecture, American Academy of Optometry, December 1981. Senior Executive Service Bonus, Department of Health and Human Services, 1981. Johns Hopkins Society of Scholars, Johns Hopkins University, May 1982. Honorary Doctor of Science Degree, Scheie Eye Institute, University of Pennsylvania, November 1982. Member, Institute of Medicine, January 1983 to present. Speaker, XIV Jules Stein Lecture, Los Angeles, California, April 1983. Recipient, Special Award of Honor, The Juvenile Diabetes Foundation, June 1983. Recipient, David Rumbough Memorial Scientific Award, The Juvenile Diabetes Foundation, June 1983. Recipient, Presidential Rank Award of Meritorious Executives, 1983. Lecture, New York Academy of Medicine, New York, N.Y., March 1984. Bowman Lecture, The Ophthalmological Society of the United Kingdom, London, England, April 1984. Recipient, The Lighthouse Pisart Vision Award, October 1984. Lecture, Howard University Hospital, Washington, D.C., December 1984. Member, Board of Trustees, Helen Keller International Inc., 1975 to present. Coordinator for USA, US-Japan Collaborative Agreement in Vision Research, 1976-1982. Organizer, Oxford Assembly, International Agency for the Prevention of Blindness, (IAPB) 1978. Coordinator for USA, Priority Area "Eye Diseases," US-USSR Program for Health Cooperation, 1978-1981. Speaker, General Assembly of the World Council for the Welfare of the Blind, Antwerp, August 1979. Director, WHO Collaborating Center for the Prevention of Blindness, National Eye Institute, Bethesda, MD, 1979. President, IAPB, 1982 to present.

## STATEMENT OF BETTY H. PICKETT

I am pleased to present the FY 1989 budget request for the Division of Research Resources (DRR). The Division of Research Resources develops, supports, and administers research resources through five multicategorical programs of specialized research facilities and environments: The Clinical Research Program; the Biomedical Research Technology Program; the Laboratory Animal Sciences and Primate Research Program; the Biomedical Research Support Program; and the Minority Biomedical Research Support Program. I will mention each program briefly, and give you an example or two of the more than 15,000 projects which these resources facilitate each year.

The 78 General Clinical Research Centers (GCRC) provide the research resources, facilities, and environments for over 4,400 studies funded by the NIH research institutes and other sources. These Centers provide the specialized clinical research settings and specialized medical and paramedical personnel, research nurses, dieticians, biostatisticians, computerized data management and analysis, and specialized laboratories. Each year, 35-40 junior physician faculty members (Clinical Associate Physicians) work within GCRCs under research mentors to gain the experience needed to become clinical investigators.

The research conducted in the GCRCs spans all NIH-supported fields of study. For example, investigators at the Yale University School of Medicine have identified the probable genetic site of an inherited form of cancer known as multiple endocrine neoplasia type 2A. Because half the members of families have the genetic defect responsible for this form of cancer, all family members must be screened using serial blood tests every 6 to 12 months. The identification of the abnormal gene will eliminate the need for annual or semiannual screening and identify those individuals at risk so that prophylactic definitive therapy can be performed before a malignancy develops.

Kawasaki syndrome, a febrile condition which affects primarily young children, is frequently associated with coronary artery aneurysm and therefore higher risk of sudden death, myocardial infarction or chronic coronary artery insufficiency. In a study involving several Centers, it was found that children with Kawasaki Syndrome treated early with both intravenous gammaglobulin and aspirin had lower incidence of coronary artery abnormalities than children treated with aspirin alone.

Research animals can provide models of diseases for the study of today's most pressing health problems--heart disease, cancer, degenerative neuromuscular disease, and AIDS. The Laboratory Animal Sciences and Primate Research (LASPR) Program supports the necessary animal resources for research in the seven Regional Primate Research Centers and in research and animal diagnostic laboratories across the nation. The LASPR also supports training of research specialists in laboratory animal sciences, and provides grants for the improvement of laboratory animal facilities, and for other animal resources which undergird the NIH's extramural research programs. LASPR also develops animal and non-animal biomedical models (lower vertebrates, computer simulations and in vitro systems) which can enhance or reduce the use of research animals, and disseminates information on their use; and participates in developing guidelines for the humane care and use of animals in research.

Some biomedical research depends on the use of nonhuman primates. For example, a disorder can be induced in monkeys that is almost identical to Parkinson's Disease in people. A treatment that involves the transplantation of adrenal dopaminergic cells into the brain has been developed and tested in monkeys with this disorder. The clinical improvement of affected monkeys following this treatment has provided the basis for a therapeutic approach now in a few patients, where the initial results have been encouraging.

Many important questions in biomedical research cannot be answered, or even explored, without access to advanced technology. Through the Biomedical Research Technology Program, the latest advances from the physical sciences and engineering are directed to biomedical research problems and made widely available to researchers.

For example, at the Resource for the Study and Control of Pharmacokinetic Systems at the University of Southern California School of Medicine, personal computer software has been developed that optimizes the dosage of drugs with narrow margins of safety.

Currently, the software is used by approximately 150 universities and major teaching hospitals worldwide. These computer programs are especially useful for administering aminoglycoside antibiotics for infections (including those occurring in patients with AIDS), drugs for respiratory and cardiac rhythm disorders, and chemotherapy for cancer. These programs will soon be suitable for routine use by community hospitals.

Cryo-electron microscopy of frozen, hydrated specimens coupled with computer image processing is a powerful tool for studies of the three-dimensional structures of viruses. This new technique, developed by scientists at the Resource for Three-Dimensional Electron Microscopy of Macromolecules, at the University of Arizona in Tucson, is being applied to studies of rotaviruses. Members of this family of viruses are the major causative agents of acute infantile gastroenteritis in humans and a wide variety of animals, and are responsible for over a million human deaths annually, particularly in developing countries.

The Biomedical Research Support Program promotes innovation in the biomedical sciences and strengthens the research infrastructure at those institutions most actively engaged in health research through three subactivities: the Biomedical Research Support Grant (BRSG) Program, the Minority High School Student Research Apprentice (MHSSRA) Program, and the Shared Instrumentation Grant (SIG) Program.

BRSG funds frequently support the pilot projects of new, young faculty members that can lead to highly competitive grant applications. For example, a new Assistant Professor of Internal Medicine at the University of Michigan's Division of Rheumatology, received BRSG funds to identify unique or functionally important cell-surface molecules on synovial T-lymphocytes from arthritic patients and to investigate the function of these surface molecules. Using the preliminary data obtained in this study, the young physician competed successfully for an NIH First Independent Research Support and Transition (FIRST) Award.

The Minority High School Summer Student Research Apprentice Program provides health-related research experiences to minority high school students in the expectation that some of the apprentices will become interested in careers in research related to health. These students work with scientists for eight weeks in basic and clinical laboratory research. Approximately 300 institutions apply for the MHSSRA Program each year. Since 1980, the program has funded 5,838 summer apprentices.

Since 1982, the BRS Shared Instrumentation Grant (SIG) Program has provided funds for the acquisition of 711 state-of-the-art instruments in the $100,000 to $300,000 cost range to be shared by groups of Public Health Service-funded investigators. For 1989 the ceiling will be raised, in accordance with recommendations from the National Advisory Research Resources Council, to $400,000.

Using an instrument provided by this program, a plasma desorption mass spectrometer (PDMS), an investigator at the Mayo Clinic has developed a new approach for finding unexpected changes in recombinant DNA peptide and protein products. Samples of the product are weighed using the PDMS. If they differ from expected weights, changes have occured. In the future, as more recombinant DNA proteins are made commercially as hormones and drugs, this "PDMS-mapping" approach may provide a rapid and relatively inexpensive method of checking that the protein material produced is indeed what it is supposed to be.

The overall goal of the Minority Biomedical Research Support (MBRS) Program is to increase the number of underrepresented minorities in biomedical research. By increasing the research capabilities of institutions with large numbers of minority students, MBRS awards foster faculty and minority student participation in biomedical research. In 1987, these grants supported the research efforts of 844 faculty members on 798 projects, and research positions for 1,107 undergraduate and 410 graduate students.

Michael A. Vigil, M.D., and Frank Perez, Ph.D., are two of over 1,100 former MBRS students who have earned doctoral degrees. Dr. Vigil, now a Research Associate Professor and Director of Occupational Health and Medicine for the New Mexico State University Primate Research Institute, became a surgeon but soon found that his interests were in research. He returned to the laboratory and is now involved in AIDS research with chimpanzees at the Holloman Air Force Facility in Alamogordo, New Mexico.

Dr. Perez, holds a Fellowship from the National Institute of Diabetes, Digestive and Kidney Diseases (NIDDK) to do postdoctoral studies at Pennsylvania State University in hormone secretion in somatotropic cells. He is also part of the team at the Pennsylvania State Center for Cell Research, involved in experiments for future space shuttle flights.

Mr. Chairman, the request for the Division of Research Resources is $319,977,000. I would be pleased to answer any questions.

## BIOGRAPHY OF BETTY H. PICKETT

Date and Place of Birth: Feb. 15, 1926, Providence, Rhode Island

Marital Status: Married to James McPherson Pickett, 1952

Education: 1945 - A.B. (Psychology) Magna Cum Laude, Brown Univ.
1947 - Sc.M. (Psychology) Brown University
1949 - Ph.D. (Psychology) Brown University

Positions Held:

| | |
|---|---|
| September 1949 - March 1958 | Assistant Professor at University of Minnesota and University of Nebraska; Lecturer in Psychology, University of Connecticut; Professional Associate, Bio-Sciences Information Exchange, Smithsonian Institution, Washington, D.C. |
| March 1958 - March 1961 | Executive Secretary, Behavioral Sciences Study Section; Executive Secretary, Experimental Psychology Study Section, Division of Research Grants, NIH |

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| August 1962<br>June 1977 | - National Institute of Mental Health: Research Consultant to Mental Health Unit, Region #1, Executive Secretary, Research Career Program; Chief, Cognition and Learning Section, Behavioral Sciences Research Branch; Deputy Director, Division of Extramural Research Programs; Director, Division of Special Mental Health Programs; Acting Director, Division of Extramural Research Programs |
| June 1977<br>January 1979 | - Associate Director for Extramural and Collaborative Research Program, National Institute on Aging |
| January 1979<br>July 1981 | - Deputy Director, National Institute of Child Health and Human Development |
| July 1981<br>July 1982 | - Acting Director, National Institute of Child Health and Human Development |
| July 1982<br>September 1982 | - Deputy Director, National Institute of Child Health and Human Development |
| October 1982<br>Present | - Director, Division of Research Resources |

Professional Societies: American Psychological Association; Eastern Psychological Association; Psychonomic Society; American Association for the Advancement of Science

Honors, Awards: Phi Beta Kappa, 1945; Sigma Xi, 1945; University Fellowship, Brown University, 1947-48; A.B., Brown University, Magna Cum Laude, high honors in psychology; DHEW Superior Service Award, 1972; DHEW Distinguished Service Award, 1975; FEW Award for Distinguished Service in Support of Equal Opportunities for Women, 1975; Citation from Graduate School, Brown University, for scientific and professional achievement, 1978; Harold M. Hildreth Award, 1979, American Psychological Association (for distinguished contribution to psychology in the public service); Senior Executive Bonus Award for outstanding performance, 1981, 1982, 1983, 1984, 1986, and 1987

### NIH PROCUREMENT SYSTEM

Senator CHILES. The committee is aware of five internal reports that have been issued over the last 5 years by the inspector general and various assistant secretaries within the Department pointing out the weaknesses in the NIH procurement system. To resolve this issue, NIH argued for the need for an independent analysis of its procurement system. That report was issued February 11, 1988, and was conducted by the Logistics Management Institute.

The report found that the NIH material support system is extremely responsive but falls short on economy and compliance. For example, the report found that procurement productivity could be improved by nearly 40 percent, saving nearly 100 work-years annually.

The inspector general in his April 15 letter, barely 10 days ago, notes that $26 million in precious research funds are being lost each year due to inefficiency and mismanagement.

The inspector general also notes failure to act could undermine public confidence in NIH's ability to provide proper stewardship over the funds appropriated for biomedical research. Additionally, the inspector general stated for the last 5 years NIH has offered only arguments and hollow promises with little overall progress in addressing the noted problems.

Dr. Wyngaarden, these reports over the last 5 years have been issued during your watch. What is NIH doing to improve its procurement program and to ensure compliance with the Federal procurement law requiring competitive bids?

Dr. WYNGAARDEN. I am pleased to have a chance to address that issue, Mr. Chairman. I would like to do so by starting back a little further than 5 years.

A number of years ago, when Dr. Fredrickson was the NIH Director, there was a serious problem within the NIH, affecting the conduct of research and reflected in a low moral among the intramural scientists, primarily because of the inadequacies of the procurement system. At that time, Dr. Fredrickson reorganized the Office of the Director and established the Office of Research Services. He persuaded Dr. Becker, who had been an intramural scientist for over 20 years at that time and had emerged as a spokesperson for the intramural scientific community, to essentially put aside his scientific career—and he was and remains a world-class authority in nuclear magnetic resonance studies—to take direction of this new office.

Dr. Becker began the reorganization process, completing each division in turn: the Division of Safety, the Division of Engineering, and then the Division of Procurement and its parallel Division of Logistics. Over the ensuing years, Dr. Becker has brought the Office of Research Services to a point where intramural research now functions very smoothly, the morale is very high, and the intramural scientists think Dr. Becker walks on water.

I want to stress that for the record because I want to be sure that we look at the positive accomplishments of Dr. Becker's tenure, as well as the points that you raised.

It is true we have been faulted in terms of fiduciary responsibility and from time to time on compliance with regulations. In the latter case, however, the problems can be attributed to relatively minor events of recordkeeping and perhaps interpretation of which small contracts need to be competed and which do not. The estimates of fiscal loss are just that, and we have agreed that there is some substance to the claims of the inspector general. However, we do disagree seriously with the magnitude of them. We think the figures are much, much smaller than $26 million, which has been lifted out of the air and has assumed a life of its own.

Nevertheless, we do agree that progress in rectifying some of these management defects, which Dr. Becker inherited, incidentally, and on which progress has been made, is not as rapid as it should be and that we need to give more attention to the matter of fiduciary responsibility and compliance. At the insistence of the Department, we have made several changes.

## ORGANIZATIONAL CHANGES

First, the Division of Procurement and the Division of Logistics are being transferred to the Office of Administration under Mr. Jack Mahoney.

Next, we are appointing an acting director of the remaining components of the Office of Research Services, and we are arranging for an SES reassignment for Dr. Becker.

Senator CHILES. Dr. Becker is going to be reassigned?

Dr. WYNGAARDEN. Yes, sir.

Senator CHILES. And procurement is going to be moved from ORS?

Dr. WYNGAARDEN. Yes; it is being moved. Functionally, it has already taken place.

Senator CHILES. Who will be in charge of procurement now?

Dr. WYNGAARDEN. It will be under the Office of Administration, which is headed by Mr. John Mahoney, Associate Director for Administration. He is in the process of recruiting a new individual to supervise the Divisions of Procurement and Logistics.

Senator CHILES. Well, I can well understand that the troops would like somebody that gets the material to them very quickly and doesn't take any time. On the other hand, when we are talking about the amount of money that NIH is spending, there has got to be credibility.

Dr. WYNGAARDEN. We agree, even though, as I pointed out, our estimates of slippage are far below those that have been indicated. Our estimates are not the result of a formal audit, but are based on the informed judgment of people who know procurement. Nevertheless, I agree with you that we need to make a change.

Senator CHILES. Well, that may be right, and there is no way I can judge that. But when you have an inspector general that says for 5 years we have been issuing these reports and nothing has been happening, that is something that gives me concern.

Dr. WYNGAARDEN. I think that's a bit of hyperbole. Much progress has been made, Senator Chiles, but perhaps not at the rate that it should have been.

### CONSOLIDATED OFFICE BUILDING

Senator CHILES. What will happen now? You are asking us for authority for a major new lease-purchase facility. Who will be in charge of that, if that authority is given?

Dr. WYNGAARDEN. That would be under my office, arranged primarily by the Division of Engineering Services, a component of ORS. We are about to appoint an acting director, probably before the week is out.

Senator CHILES. Well, I have heard from a number of sources, including Senator Mikulski, that there is an interest in construction of a new office building on the NIH campus to permit you to consolidate people from four off-campus facilities and that you would need this lease-purchase authority.

I understand the annual lease payments will be less than the rent you are currently paying. Is that correct?

Dr. WYNGAARDEN. Yes; using OMB techniques, called net present value, we estimate that that would save $65 to $70 million over the next 20 years, at which time we would own the building.

Senator CHILES. As this moves along, we would like to be very well informed about it and what you are proposing to do and how you are proposing to oversee this.

Dr. WYNGAARDEN. We'd be happy to do that.

### OVERSIGHT RESPONSIBILITY

Senator CHILES. A recent Jack Anderson article in the Washington Post claims that the potential for fraud in NIH-sponsored biomedical research is high. Representative Dingell has stated that the NIH oversight over potentially fraudulent science is in his words "hopelessly inadequate."

What are your thoughts on this issue and how serious is it?

Dr. WYNGAARDEN. We have a certain number of complaints every year, and we take every allegation of fraud seriously. Perhaps 15 to 20 come to our attention officially.

Senator CHILES. How many people do you have handling those?

Dr. WYNGAARDEN. In the Office of the Associate Director for Extramural Research and Training, we have two full-time professionals plus support staff who are doing this. It is likely that we will add two more people to this office. However, it should be noted that this office works closely with our legal office, our internal audit staff, and the scientific program staff, so the available resources are much greater.

Senator CHILES. What kind of expertise do these people have? Are they trained investigators? Do they have any expertise in audit or investigative work?

Dr. WYNGAARDEN. They have experience. One of the individuals we are considering adding to this group has considerable training as an investigator. Dr. Raub knows him personally and could speak to that.

Dr. Raub. In addition to the individuals in the central office who manage and coordinate these various investigations, we have a separate standing audit investigative unit that has a broad range of responsibilities, one of which is to assist the central office with respect to these investigations of possible misconduct in science.

Senator Chiles. Well, if you have 20,000 grants or over 20,000 and you have two professionals that look at that, it is a little bit maybe like IRS dropping their audit procedures down to where less than 1 percent of the people know that they are going to be audited. All of us start off wanting to do right, but nothing helps us do right a little bit better than knowing that somebody might be looking over our shoulder sometime to determine whether we are doing right. How many cases have you brought in these 20,000 grants in the last 5 years?

Dr. Wyngaarden. We have about 20 cases brought to our attention per year.

Senator Chiles. Those are the allegations. What has ripened from that?

Dr. Wyngaarden. About one-half disappear very quickly when the investigations show that there are misunderstandings or perhaps vendettas between people who have fallen out. The remaining cases are substantial events that require further investigation, and a few of those each year represent very serious episodes of misconduct or fraud.

The system that has developed over the last 5 to 10 years with the help of many professional societies and study groups places the primary investigative responsibility on the grantee institution. When an event is reported, the grantee institution conducts a preliminary review, and if the institution finds substance to the allegation, it is brought to our attention along with the institution's proposed plan for investigation. If the plan appears initially adequate, we wait for the report of the institution. If it appears to be a very major case, we may proceed immediately with an NIH investigating committee. If the institution seems to have handled it well, we review the report and take whatever measures are necessary.

In certain cases we appoint our own investigative committee to conduct a parallel investigation. Either approach may result in sanctions being recommended and actually levied. We have debarred a number of scientists. We have placed others under other types of restrictions.

### AUDIT PROCEDURES

Senator Chiles. Do you have a procedure in which you do some kind of random audits?

Dr. Wyngaarden. There are fiscal audits, and data audits of studies involving investigational drugs, but we don't have any sort of random visits to laboratories to check the authenticity of claims.

Senator Chiles. Well, I don't know enough about your projects to even pose this question almost. But the IRS, for example, does some crosscuts in which they just look for certain signals. If your charitable contributions are too high, if you do have certain things, then they look further. On the other hand, they have sort of a random selection in which they go in and they pick out some poor devil, and they say we are going to look at everything bought and everything you have purchased, and you get a top to bottom kind of lookover. And that is the one that makes a lot of us I think decide we better file properly.

Dr. WYNGAARDEN. I think science does not lend itself to that kind of approach. We have placed that responsibility on the grantee institution to monitor the scientists who are actually members of that faculty or research staff.

Again, I don't know whether we do it quite the way you are describing it, but the fiscal audit would perhaps show any kind of impropriety. A team of auditors visits all grantee institutions and examines their resources. They may disallow certain expenditures that are claimed. They also establish the indirect cost rate, as you know, from audits of the books of that institution.

Perhaps Dr. Raub, who has been very close to this, would like to comment.

Dr. RAUB. There is nothing I can add on the fiscal side, but there is not a counterpart to the fiscal audit in the sense of inspection of laboratory notebooks and the like. All of our efforts and that of the universities to date have been principally on the promotion of proper practices and on emphasizing the critical importance of faithful execution of the canons of science. Otherwise we put our energy into the investigations of particular cases that come to our attention through allegations or because there is some reason to suspect wrongdoing or possible error in the work.

Dr. WYNGAARDEN. We do conduct some site visits of applications. We don't do as many as we have done in the past, largely for fiscal reasons. But particularly in large applications, we may convene a team to visit the scientists and review the proposal, all the facilities, and the adequacy of the staff for that kind of project. Frequently a site visit plays a heavy role in whether the application is funded.

Senator CHILES. But at the same time, very much a part of that project is to be able to audit results, audit what is going on.

Dr. WYNGAARDEN. Yes.

## SCIENTIFIC ACCOUNTABILITY

Senator CHILES. I think it is one thing talking about whether we are going to decrease the paper work—and I'm 100 percent for that—but there has to be accountability, and there has to be the ability to follow the trail and determine whether people are being proper stewards of the funds that they are receiving.

Dr. WYNGAARDEN. Each grantee submits an annual progress report and a terminal report designed to provide information of that sort. It is not quite the audit that you indicate, and we have really shied away from the idea of unannounced site visits to look at the propriety of the conduct of research because we continue to believe that the vast majority of scientists are very highly principled individuals and that the yield of such visits would be very small. Unless there is some specific complaint, we have not done that.

Senator CHILES. Well, it may be that there is a self-policing working here and that is something to look at. But I caution you. Nothing undermined the strong sort of consensus that was present for increases in the defense budget more than when it began to unravel and it began to talk about from the toilet seats to the hammers to then major fraud perpetuated by some of the outstanding, leading corporations and businesses in this country, and nothing undermined that credibility and that consensus faster than that. And I think that we would hate to see something undermine the consensus that we again seem to have in trying to go forward in the research programs that we have.

Dr. WYNGAARDEN. Yes; we agree. There is no question that we have been wounded by these episodes of misconduct and fraud.

I would also agree with your last point. I do think the system is self-policing. It may not be as rapidly responsive as it should be, and it's a developing field in which institutions are learning how to deal with these events. Many of them have not done as well the first time as in later events in their institutions, but I think we are on the right track. Serious episodes of fraud are sooner or later uncovered because they produce data that are just not consistent with reality, and other investigators doing similar work discover that.

## PROPOSED REORGANIZATIONS

Senator CHILES. Doctor, as you know, there are a number of reorganizational issues under consideration for NIH. Labor and Human Resources recently reported out the NIH reauthorization bill, and that legislation would create a new institute for deafness.

Additionally, there is an interest among some groups in having the Institute of Mental Health taken over by NIH and an interest in having NIH assume Governmentwide responsibility for rehabilitation research.

I wonder if you would comment on each of these reorganizational issues.

Dr. WYNGAARDEN. We have a substantial existing program in research on deafness and hearing impairment, primarily centered in the National Institute of Neurological and Communicative Disorders and Stroke. Funding is in the range of $70 or $80 million. There is perhaps another $10 million of research funded by several other institutes, including the National Institute of Child Health and Human Development and the National Institute on Aging.

Dr. Goldstein, the NINCDS Director, will be happy to speak to the details of that program when he testifies.

We think that the program on deafness and hearing impairment is proceeding well, but could receive more emphasis. A few hearing centers are underway, and it has been suggested that more of those would be worthwhile.

Whether a new entity is necessary is really as much a political as a scientific issue. We do think that the science is being very aggressively pursued under the existing arrangement. But that, obviously, is a decision that the Congress will make.

With respect to the rehabilitation issue that you mention, research is going on in quite a number of our institutes, with total funding of $105 million this year. We feel very strongly that the rehabilitation research we are conducting should remain tethered to its scientific base. Rehabilitation studies involving the nervous system ought to be done in the Neurology Institute; those involving the skeletal system, in the Arthritis and Musculoskeletal Disease Institute; efforts involving cardiovascular and cancer problems, in those appropriate institutes. We would be opposed to lifting that research out of those current institutes and placing it in a new one.

I know the issue that you are raising also involves programs currently not conducted within NIH, and we have no official position on that. We are not acquainted with the arguments for moving that or leaving it where it is.

With respect to the National Institute of Mental Health and its sister institutes in the Alcohol, Drug Abuse, and Mental Health Administration, I know that there are certain professional societies and public interest groups that are promoting the transfer, particularly of NIMH, to NIH. As I have said many times, we are comfortable either way. The Department is opposed to that transfer at this time, suggesting instead a minor reorganization within ADAMHA and maintaining the separate identity of that agency.

I would add, however, that our working relationships with all three of these institutes, and in particular NIMH, are very close. The NIMH intramural program is largely on the campus at NIH, where they have laboratories and clinical center space. NIMH also participates in our committees, so the working relationship will remain close under any sort of organization.

## HUMAN GENOME PROJECT

Senator CHILES. Last year the committee provided $17.5 million to begin the gene mapping effort. The request this year is for $28 million, and I understand that a recent NIH conference suggested this total increase each year up to $200 million for 15 years for a $3 billion effort. The Energy Department has requested $15 million for 1989 and is spending $10 million this year.

How do you coordinate your efforts with the Department of Energy, and when will the administration appoint a lead agency?

Dr. WYNGAARDEN. As I mentioned in my prepared testimony, we are organizing a special Office for Human Genome Research headed by an associate director. We will also appoint a program advisory committee to oversee this development with us.

The coordination of our efforts occurs, first of all, within NIH. We expect that the program advisory committee will be primarily advisory to NIH. The Department of Energy has its program advisory committee. We have suggested that there be cross-membership on those committees so that we maintain close communication.

In addition, there is a human genome committee under FCCSET, the Federal Coordinating Council on Science Engineering and Technology, under OSTP. That committee brings all the participating agencies and departments together, including NIH and the Department of Energy. It also includes the National Science Foundation, which supports work in this area. I think we have the rudiments of good coordination both within and across the Government.

We also have a growing and evolving coordination system on the information handling front. There are currently two major banks that handle information related to sequences and repositories. With respect to sequences, we have the GenBank, which is largely financed by NIH and operated by the Department of Energy. The European counterpart of that is the European Molecular Biology Laboratory data bank. Japan is now starting one called the DNA data bank of Japan. These three operations are in different spheres of activity but are linked so that information is exchanged and freely available.

The Biotechnology Information Center that is proposed at the National Library of Medicine would carry this coordination even further by evolving common languages and central data bank linkages such that all of the data banks would be available to all scientists through a single contact point. Many other types of data banks, such as protein data banks and probe data banks, need to be coordinated.

We have made good progress in this evolving field. One of the purposes of having these advisory committees of outstanding scientists is to make sure that, year by year, we are moving in the right direction with a project that could become very large.

The figures that you mentioned of $200 million a year for 15 years are the recommendations and estimates of a committee of the National Research Council. Many of the members of our ad hoc advisory committee had served on that committee also. Consequently, we had all the available information being brought to bear on the NIH plans.

## FOCUS FOR HUMAN GENOME PROJECT

Senator CHILES. My understanding is the Office of Technology Assessment, who is going to issue a report tomorrow, has pointed out that there are a number of related genome efforts being conducted by several agencies. The National Institutes of Health and the Department of Energy are the principal agencies involved. Legislation currently before the Congress, including S. 1966 that has been approved by the Labor Committee, emphasizes the importance of interagency cooperation.

Your budget proposal provides this money that we talked about. I recently had the opportunity to visit Los Alamos, the national lab, and was impressed by the cooperation between the Los Alamos scientists and NIH researchers. The Department of Energy, as we said, is asking $18.5 million in genome funding for fiscal year 1989.

How are we going to really determine who will really be making these decisions, recognizing that this is something that all of these areas have an interest in and that is well that they should have, but that there needs to be some kind of coordination or some kind of control or some kind of a lead agency here?

Dr. Wyngaarden. I would like to answer that in two parts.

Senator Chiles. And also, again, so we can have accountability.

Dr. Wyngaarden. I would like to stress how this field has developed. The major player in the development of genetic information and genetic research has been the National Institutes of Health for 20 or 30 years. Much of the early work on bacteriogenetics, bacteriophasia, was NIH supported. A number of Nobel Prizes have been given in this area. Almost all of those were awarded to scientists supported by the NIH over the years.

We have focused that type of research most recently on specific genes of interest, genes that we know produce certain proteins or cause certain diseases.

We are currently funding about $440 million in research areas related to human genetics and the undergirding biotechnology, DNA research, and so on. Of that, over $100 million is in human disease research. When we analyze the total field of biotechnology, which includes genetics and related areas of immunology, the NIH is by far the biggest player. Our total resources in biotechnology are on the order of $2.4 billion per year. The rest of the Federal Government is about $400 million.

I cite these figures to indicate that the NIH has really opened this field, developed it, and brought it to the stage where sequencing and mapping the human genome is possible. Other agencies have played some role, but, quantitatively, nowhere comparable to the NIH investment.

Furthermore, the reason for exploring the human genome, for proceeding with detailed mapping and ultimately sequencing, is to be able to extract the biological information and make use of that information in the study of human disease. And that again is an NIH mission.

So, if there is to be a lead agency, it seems to me there is only one logical place, and that is at the NIH.

Senator Chiles. That's a very good argument. When I hear certain of the Los Alamos players, they say who has the capacity to do this now, who has the computers, who has the ability to do it. It's us. And why should we not be turned loose and able to do this project and get it the heck done where then people could use it?

Dr. Wyngaarden. My argument is not to exclude Energy or NSF or any other agencies. It's a big project, and we can use the assistance of many groups in this country and overseas.

Senator Chiles. Obviously, I think we have to use all of our players.

Dr. Wyngaarden. Absolutely, but the reason for going forward with this project is because biological information is of relevance to human disease and will lead to a further understanding of the human organism.

## COORDINATION OF EFFORTS

Senator CHILES. Well, back to what I said. Is the administration going to try to sort this out? Are they going to say this is the way it is going to go? Or is the ball going to be thrown to Congress and are we going to fight about it up here between our supporters of the different groups?

Dr. WYNGAARDEN. My position is that what we primarily need is a coordinated scientific advisory group so we make the wisest decisions on the research to be done, that our efforts are well coordinated, that needless duplication can be avoided, and that the proper roles are assigned to those who can best fill them.

For the present, the human genome project must proceed along the lines of a relatively small science, getting larger as time goes on. We are not contemplating in the next 6 years, perhaps, any kind of huge centers to do this as a tour de force. Much methodological work needs to be done.

We need to have some interlocking and overlapping membership on the various advisory committees that relate to the individual agencies in this project.

Senator CHILES. But somebody has to say, if there is going to be a coordinated agency, here are the players and here is who is going to coordinate, and here is how the mix is going to be, or it isn't going to get done.

Dr. WYNGAARDEN. Several bills in the House and Senate are addressing this issue. There is also the human genome committee under FCCSET that I mentioned in which all the agencies are represented. My own view is that, while we need some sort of coordinated, interlocking advisory bodies that make certain that what you propose is accomplished—and it is what we want also—it is far less important to have a lead agency than it is to have resources available. The coordination can be done by the kinds of advisory committees that we have in place now. And as they evolve, if something more is needed, we will recognize that at the time and act accordingly.

## BIOTECHNOLOGY RESEARCH

Senator CHILES. The biotechnology industry now at $750 million in sales is projected to be a $40 billion industry by the year 2000. As we discussed last year, I am concerned that foreign companies will reap the benefits of our billions in NIH research directly focused on biotechnology and beat us to the marketplace.

The committee asked NIH to recommend a program to encourage cooperative university-industry applied biotechnology research. We received your report, but it didn't include any recommendations.

You have had a conference now at NIH. What can you tell me now, after the results of the conference, in regard to the direction you're taking?

Dr. WYNGAARDEN. The conference, which you so kindly opened—and that was very much appreciated, Senator Chiles—directed a great deal of its attention to training needs. The upcoming OTA report estimates the need for additional trainees at 1,000 to 1,500 individuals. It recommends that the program for training in biotechnology be expanded with an increase of about 250 trainees per year, and it lists the specific fields in which those trainees are most needed, including structural biology and applied genetic research, chemical engineering, biological engineering, and so on, as well as support of the traditional disciplines. We are analyzing those recommendations to see what we can do to move in that direction. We think that the training investment is a very important area to highlight.

In addition, we are responding to the provisions of the Federal Biotechnology Transfer Act, with very much expanded oversight of the kind of developments that warrant patenting and licensing and making certain that those NIH intramural scientists who participate are eligible to receive those royalty proceeds to which they are entitled.

We are in the process of discussing some type of oversight with the Office of the Assistant Secretary for Health because there clearly are interests of that kind in more agencies of the PHS than just NIH.

Senator CHILES. Well, we very much want your people to work with our staff so that we can try to include some of these efforts.

Dr. WYNGAARDEN. We'd be happy to do that.

### RESEARCH PROJECT GRANTS

Senator WEICKER. Dr. Wyngaarden, the 1988 NIH appropriation provided for at least 6,100 new and competing grants. How many new and competing grants will you be able to fund under the fiscal year 1989 request of the President?

Dr. WYNGAARDEN. The request would support 5,611 new and competing research project grants plus 150 new and competing AIDS grants.

Senator WEICKER. So, roughly what? About 5,800?

Dr. WYNGAARDEN. The combined figure would be 5,761 grants.

Senator WEICKER. How is it that we are going to fund fewer grants when the fiscal year 1989 budget request provides a funding increase of more than $400 million?

Dr. WYNGAARDEN. We assigned about 90 percent of the increase to the research project grant category. However, the commitment base that results from awards made in previous years requires a substantial amount of those funds if we are to keep the downward negotiation in line. Even with the allocation of 90 percent of the increase to the research project grant category, we will be facing 13 percent downward negotiations of new and competing awards and about 10 percent for the noncompeting grants. If we were to have increased beyond the 5,611 new and competing awards, we would have been faced with up to 20 percent downward negotiations.

Senator WEICKER. What factors are calculated in the average cost of a grant? Why does the NIH current services estimate differ from CBO?

Dr. WYNGAARDEN. It has to do with the estimate of the costs of biomedical research. We have addressed this issue several times, and our best estimate derives from an algorithm developed for us by the Department of Commerce, which takes into consideration the actual price increases of goods and the salary increases in the research community.

We find that the average cost of research increases each year approximately 2 percent more than the GNP deflator. If one doesn't factor that in, of course, one gets a much lower average cost of research in the out-years of a multiyear award. But that 2 percent per year, of course, is based on experience.

Senator WEICKER. Well, I have to say that I thought we were making progress, but we have about 300 to 400 fewer grants for this coming year than we had last year.

Dr. WYNGAARDEN. Yes; that is right. And that level was possible only by holding almost all other areas of the budget constant. We have small increases in the general clinical research centers, career awards and training, and obligatory increases in the intramural program. Almost everything else in the budget has been straight-lined in order to assign 90 percent of the increase to the research project grant category.

## CLINICAL TRIALS

Senator WEICKER. How many clinical trials will we fund in 1988?

Dr. WYNGAARDEN. In 1988 we're funding 43 major new clinical trials.

Senator WEICKER. How many would be funded under the President's fiscal year 1989 request?

Dr. WYNGAARDEN. There would be 14 additional major new clinical trials in 1989.

Senator WEICKER. How many?

Dr. WYNGAARDEN. Fourteen, nine by the Cancer Institute, two by the Dental Institute, and three by Child Health.

Senator WEICKER. Just so that I don't misinterpret the numbers that you're giving me, as I understand it, we have 43 clinical trials that will be funded in 1988.

Dr. WYNGAARDEN. Yes; 43 new ones.

Senator WEICKER. New ones.

Dr. WYNGAARDEN. Yes.

Senator WEICKER. And for 1989, 14 new ones. Right?

Dr. WYNGAARDEN. In 1989 there would be 14 additional new ones, yes. Most of those are multiyear trials, of course.

Senator WEICKER. And for the record, could you please tell us what clinical trials have been approved and are ready to go, but won't be started because of the lack of funds?

Dr. WYNGAARDEN. There are 98 others that could be funded if funds were available. We can provide a list of those, if you would like, for the record.

Senator WEICKER. Yes; I would like a list of them.

[The information follows:]

National Institutes of Health

## MAJOR NEW CLINICAL TRIALS READY TO BEGIN IN FY 1989 IF FUNDS WERE AVAILABLE

(Dollars in thousands)

| NCI | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| Clinical Cooperative Groups -- Increased patient accrual for high-priority trials | $5,000 | $25,000 | 3 |
| Growth factor/anti-oncogene therapy trials -- Provision for full funding | 1,500 | 3,000 | 2 |
| Use of novel radiolabeled monoclonal antibodies for cancer therapy | 300 | 950 | 3 |
| Additional phase I/II trials of newly characterized biological response modifiers (BRMs) for treatment of various cancers | 4.000 | 4,000 | 1 |
| Developmental and clinical testing of monoclonal antibodies | 10.000 | 20.000 | 2 |
| LAK/IL-2 studies -- Use of adoptive immunotherapy in additional cancer types and use as an adjuvant treatment | 10.000 | 50.000 | 7 |
| Pilot studies in prevention of nasopharyngeal cancers | 169 | 843 | 5 |
| Modification of diet for prevention of gastric cancers | 700 | 3.500 | 5 |
| Lung cancer prevention studies -- Provision for full funding | 1.148 | 3,900 | 8 |
| Clinical/Comprehensive Cancer Centers -- Increased support | 25,000 | 125,000 | 5 |
| Increased accrual to double patient entry into clinical trials | 27.000 | 125,000 | 5 |
| Studies of the efficacy of hyperthermia in cancer treatment protocols | 2,500 | 13,530 | 4 |
| Total, NCI | 87,317 | 374,725 | |

| NHLBI | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| Trial for prevention of platelet alloimmunization | $500 | $8.562 | 6 |
| HMG CoA reduction inhibitors in older population | 1.875 | 59,917 | 10 |
| Alcohol restriction in treatment of hypertension | 246 | 1,846 | 5 |
| Membrane-active agents to prevent sickle cell disease | 500 | 3,000 | 3 |

UNFUNDED CLINICAL TRIALS: FY 1989 (Continued)

| | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| **NHLBI (Continued)** | | | |
| Digitalis and congestive heart failure | $200 | $6,500 | 7 |
| Continuous positive airway pressure for treatment of sleep apnea | 1,200 | 10,000 | 6 |
| Therapy in patients with peripheral arterial disease | 1,000 | 54,500 | 10 |
| Pharmacologic intervention in respiratory distress syndrome | 750 | 20,000 | 5 |
| Prevention of myocardial infarction in unstable ischemic states | $1,000 | $30,000 | 7 |
| Antiarrhythmics and beta-blockers study | 2,000 | 45,000 | 8 |
| Clinical measure of elevated blood pressure in children | 2,300 | 24,000 | 8 |
| Treatment of idiopathic fibrotic lung disease | 1,000 | 30,000 | 6 |
| Differential efficacy and safety of antihypertensive drugs in the treatment of hypertension | 1,500 | 11,500 | 10 |
| Trial of fish oils for the prevention of coronary heart disease | 3,000 | 35,000 | 7 |
| Treatment of Pneumocystis carinii pneumonia | 600 | 12,000 | 5 |
| Total, NHLBI | 17,671 | 351,825 | |
| **NIDR** | | | |
| Use of adhesive sealants to restore root surface caries lesions | 100 | 200 | 3 |
| Use of remineralizing solutions to reverse incipient caries lesions | 100 | 200 | 3 |
| Testing of alternative preventive measures for the prevention of dental disease in individuals with limited ability to perform appropriate oral hygiene procedures and limited access to routine dental care | 225 | 675 | 3 |
| Evaluation of the impact of alternative restorative modalities on the mortality of teeth in adults | 200 | 2,000 | 10 |
| Total, NIDR | 625 | 3,075 | |

UNFUNDED CLINICAL TRIALS: FY 1989 (Continued)

| NIDDK | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| Diet and exericse in the prevention and treatment of noninsulin-dependent diabetes mellitus | $500 | $2,600 | 5 |
| Enzyme replacement therapy in severe combined immunodeficiency states | 300 | 1,000 | 3 |
| Drug therapy of chronic disabling diarrhea | 1,200 | 2,800 | 3 |
| Use of erythropoietin in pediatric patients with renal failure | 1,000 | 5,500 | 5 |
| Impact of dialysis efficiency in response to erythropoietin treatment | 250 | 850 | 3 |
| Pharmacologic prevention of cholesterol gallstones during rapid weight loss regimens | 1,300 | 3,000 | 3 |
| Treatment of primary biliary cirrhosis using ursodeoxycholic acid | 1,000 | 5,630 | 5 |
| Nutritional therapy in cystic fibrosis | 300 | 1,600 | 5 |
| Therapy of children with short stature due to growth hormone deficiency | $1,000 | $5,500 | 5 |
| Neonatal diagnosis of cystic fibrosis | 750 | 2,500 | 3 |
| Total, NIDDK | 7,600 | 30,980 | |

| NINCDS | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| Use of copolymer I in the treatment of acute optic neuritis and multiple sclerosis | 600 | 2,550 | 4 |
| Study of cyclosporin A for the management of autoimmune disorders such as myasthenia gravis and Guillian Barre syndrome | 525 | 1,600 | 3 |
| Study of orphan products for treatment of rare movement disorders such as Tourette's syndrome | 1,000 | 3,122 | 3 |
| Efficacy of new antiepileptic drug | 500 | 1,000 | 2 |
| Study of surgical treatment for the management of epilepsy | 800 | 4,000 | 5 |
| Treatment of Parkinson's disease with L-Dopa | 1,500 | 7,000 | 6 |
| Study of plasminogen activators in the early treatment of stroke | 1,200 | 6,000 | 5 |

UNFUNDED CLINICAL TRIALS: FY 1989 (Continued)

| | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| **NINCDS (Continued)** | | | |
| Use of amino-steroids in the treatment of trauma to the central nervous system | $1,500 | $7,500 | 5 |
| Use of betaine for the treatment of homocystinuria (metabolic disease) not responsive to pyridoxine hydrochloride treatment | 315 | 1,100 | 3 |
| Use of vitamin E and dietary essential fatty acids (DEFA) in the treatment of Charcot-Marie-Tooth disease | 550 | 2,300 | 4 |
| Diagnosis and treatment of inner ear fluid leaks, a newly recognized cause of sudden deafness | 1,120 | 5,600 | 5 |
| Total, NINCDS | 9,610 | 41,772 | |
| **NIAID** | | | |
| Efficacy trial for acellular pertussis vaccines | 1,455 | 2,555 | 2 |
| Efficacy trial of live, attenuated, quadravalent, oral retrovirus vaccine | 1,236 | 2,892 | 3 |
| Effect of recombinant human granulocyte-monocyte colony stimulating factor in patients with child onset cyclic neutropenia | 425 | 1,174 | 3 |
| Efficacy trial of Hib conjugate vaccines | 597 | 1,992 | 3 |
| Genital herpes vaccine | 265 | 1,325 | 5 |
| Randomized controlled trial of pneumococcal immunization using linked records to assess outcome | 1,358 | 4,004 | 4 |
| Cyclosporine A treatment of pulmonary sarcoidosis | 500 | 1,500 | 5 |
| Efficacy trial of influenza A vaccine | 800 | 1,800 | 3 |
| Total, NIAID | 6,636 | 17,242 | |

UNFUNDED CLINICAL TRIALS: FY 1989 (Continued)

| NICHD | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| Efficacy of intravenous gamma globulin in the treatment of symptomatic children infected with HIV (expansion) | $3,000 | $8,000 | 3 |
| Safety and efficacy of pertussis vaccine (expansion) | 3,000 | 24,000 | 6 |
| Clinical studies with new injectables for female fertility regulation | 200 | 750 | 3 |
| Modified capronor drug delivery system (removable implant) for long-term female contraception | 220 | 500 | 3 |
| Evaluation of vitamin E in the prevention of intraventricular hemorrhage in very low birth weight infants | 180 | 375 | 2 |
| Randomized therapy of preterm, premature rupture of membranes (PROM) with prophylactic antibiotics | 1,700 | 6,000 | 3 |
| Prevention of preeclampsia with calcium supplementation | 400 | 2,400 | 4 |
| Tin protoporphyrin for the prevention of neonatal jaundice | 200 | 800 | 3 |
| Evaluation of methods to encourage smoking cessation among pregnant women | 200 | 1.000 | 3 |
| Transdermal patches for female contraception | 250 | 500 | 2 |
| Comparisons of efficacy of various available types of surfactant to treat respiratory distress syndrome | 200 | 700 | 3 |
| Randomized community trial of childhood accident prevention programs | 500 | 2.000 | 3 |
| Prevention of brain damage in asphyxiated newborn infants by using a newly developed steroid derivative | 300 | 1,000 | 3 |
| Optional nutritional management of the very-low-birth-weight infant | 250 | 1,250 | 5 |
| Use of analogues of GHRH in the treatment of growth retardation | 150 | 750 | 5 |
| Clinical study of a new testosterone derivative for male fertility regulation | 175 | 400 | 2 |
| Trial of Somatomedin-C in the treatment of growth retardation | 200 | 1.000 | 5 |
| Early vs. late enteral feeding in very-low-birth-weight infants | 200 | 600 | 3 |
| Cholecystokinin (CCK) in infants on total parenteral nutrition | 150 | 300 | 2 |
| Developmental follow-up of a randomized controlled trial of varying diets of preterm infants | 200 | 200 | 1 |
| Total, NICHD | 11.675 | 52.525 | |

UNFUNDED CLINICAL TRIALS: FY 1989 (Continued)

| | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| **NEI** | | | |
| Central vein occlusion study | $1.650 | $10.000 | 5 |
| Herpes eye disease study | 1,370 | 8,500 | 5 |
| Normative and clinical assessment of acuity cards | 380 | 1,600 | 3 |
| Cooperative amblyopia classification study | 580 | 1,200 | 2 |
| Glaucoma prevention trial | 1,010 | 15.300 | 8 |
| Thrombolysis in central vein occlusion trial | 2,600 | 19,000 | 5 |
| Surgical parameters for congenital esotropia | 1.200 | 6,400 | 5 |
| Natural history study of age-related macular degeneration | 750 | 6.200 | 7 |
| Natural history study of cataract | 750 | 6.200 | 7 |
| Vitrectomy for trauma study | 1,620 | 13.500 | 5 |
| Total, NEI | 11.910 | 87,900 | |
| **NIA** | | | |
| Interventions to reduce frailty among older persons | 2.000 | 8,000 | 4 |
| Strategies to improve drug prescribing for older persons | 500 | 2.500 | 5 |
| Total, NIA | 2.500 | 10.500 | |
| **NIAMS** | | | |
| Efficacy of calcitonin in the treatment of osteoporosis | 500 | 2.500 | 5 |
| Efficacy of 13-cis retinoic acid and other retinoid derivatives in the treatment of keratinizing disorders | 1,000 | 3.000 | 3 |
| Efficacy of sulfasalazine in the treatment of reactive arthritis | 375 | 750 | 2 |
| Use of retinoids in the treatment of psoriatic arthritis | 500 | 1.025 | 2 |
| Total, NIAMS | 2.375 | 7.275 | |

UNFUNDED CLINICAL TRIALS: FY 1989 (Continued)

| NCNR | First year cost | Total projected cost | Duration (years) |
|---|---|---|---|
| Clinical studies of nursing interventions to reduce incidence of low birth weight infants and infant mortality | $900 | $5,000 | 5 |
| Clinical studies of nursing interventions effective in the control of symptoms of virally infected patients | 1,250 | 7,000 | 5 |
| Total, NCNR | 2,150 | 12,000 | |
| Total, NIH | 160,069 | 989,819 | |

## BUDGET TRENDS AND DEVELOPMENT

Senator WEICKER. Now, here I've taken two rather key elements of the National Institutes of Health, the grants and the clinical trials. Everybody is running around here boasting about how NIH is doing very well under this budget, yet in both these instances, you are going way back.

Dr. WYNGAARDEN. I might point out the total dollars, Senator Weicker, for all clinical trials. In 1988, the dollar estimate was $472 million and, in 1989, it is $500 million, so the total budget for them has gone up.

Senator WEICKER. Yes; but I think the actual number of projects that are encompassed by these budgets are far less than the other modest increases in dollars. I think that increase in dollars is very misleading to the actual projects, either trials or grants, that are being reduced.

Now, do you feel that in some way the additional money that is being proposed to go into AIDS was derived by nicking these other areas?

Dr. WYNGAARDEN. Actually, Senator Weicker, the two budgets are developed on rather separate tracks. We construct the non-AIDS budget in accordance with specific guidance that comes to us from OMB through the Department and PHS.

We construct the AIDS budget in the reverse manner. We evaluate our needs carefully, correct for any sort of overlap among Institutes at the NIH, and then submit our budget request.

Senator WEICKER. You are not telling me that you people put together the AIDS budget, but OMB puts together the NIH budget.

Dr. WYNGAARDEN. No; not quite. We do receive guidance as to parameters for the non-AIDS budget and we construct the budget within the parameters that OMB provides.

Senator WEICKER. But in terms of a budgetary overview, we have—the point that I am trying to make is that we, in essence, have one NIH budget request. Right? It's $7,122,837,000. Now, granted you can break AIDS money out of there, but this is one request. Obviously, I have to ask myself as to whether or not we're taking from other areas, rather than the new money which has always been the basis of any reasoned approach toward the AIDS problem, to go ahead and achieve what is necessary for AIDS by your, I'm sure, honest calculations.

Dr. WYNGAARDEN. The AIDS budget is proposed for consolidation in the Office of the Assistant Secretary for Health, as you know. The only budget that we are discussing today, as far as I know, is the NIH non-AIDS component, which is 5.4 percent over 1988.

Senator WEICKER. Well, but now we have hit upon two major activities of the NIH, both of which will come nowhere near 1988 levels, grants and clinical trials.

Dr. WYNGAARDEN. You are correct; these items are not at the current service level.

Senator WEICKER. Maureen points out to me—and make no mistake about it. I intend to reject this consolidation under the Office of the Assistant Secretary for Health. That is not the law now. Is it? No.

Dr. WYNGAARDEN. I'm sorry?

Senator WEICKER. The law is not so written as to consolidate these moneys, in other words, in the Office of the Assistant Secretary of Health.

Dr. WYNGAARDEN. No; that is part of the 1989 proposal.

### RESEARCH FACILITIES

Senator WEICKER. As you know, last year this committee asked you to convene a meeting of outside experts to recommend the design, program balance, and administration of an initial pilot research facilities construction program at NIH. I understand this meeting was held in February and many of the preliminary recommendations have been included in the NIH reauthorization bill that has been reported out of the Senate Labor, Human Resources Committee.

Could you highlight some of the recommendations and do you believe this program will begin to address the facility needs at many of our institutions across the country?

Dr. WYNGAARDEN. The recommendation came in many components. The committee recognized a very large need for extramural construction to maintain the American research enterprise at a high level of productivity. It made specific recommendations with respect to levels of funding over several years, addressing both equity financing, with a 50–50 matching requirement, and debt financing, which would apply the indirect cost use allowance to construction and equipment needs.

The committee proposed a two-phase, 10-year program, beginning with a 2-year pilot phase at $100 million for year one and $200 million for year two, and then $350 million to $500 million for the remaining years with some specific additional points to be considered. These included a minimum of $250,000 per award, not more than 5 percent to any one institution in one year, and review criteria based on intrinsic scientific merit, but also taking into account the desirability of broadening the national research base of excellence in biomedical research among institutions of emerging excellence.

I would point out that this was a study and an exercise that was taken without comparing these needs with other national priorities. The report is now being reviewed within the Department; Mr. Williams may want to comment further.

Mr. WILLIAMS. The report came in draft to us a short time ago. We have reviewed it. We have sent some comments back to the National Institutes of Health and asked them to consider some other factors. I think the report, as it is currently constructed, does talk from the research community's own perspective about what their desires and needs are. And we have asked that some of that information be put into a broader perspective so that one can see the narrower needs of those broader priorities.

That report we think should be available fairly soon.

Senator WEICKER. The NIH reauthorization bill authorizes up to $150 million for facility construction. I gather that falls somewhat short as to what you feel is necessary.

Dr. WYNGAARDEN. The committee looked at this primarily from the standpoint of new Federal financing. The other side of that, of course, is that many institutions have found it possible to borrow construction money and then introduce into the indirect cost reimbursement pool the money costs themselves, as well as the depreciation allowances. Although that is another mechanism to achieve some of these same goals, it is not available to all institutions. We probably need some combination of the two.

The estimates from the committee are, obviously, rather impressive, but, as Mr. Williams points out, they have not been considered in the context of competing priorities.

## FETAL TISSUES IN RESEARCH

Senator WEICKER. The other day I happened to read in the newspapers of a situation as it relates to the use of fetal tissues for research, or more particularly as it relates to the new procedures contemplated what is it? For Parkinson's disease?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. Am I correct on that?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. And it is my understanding that the ethical guidelines, and so forth, have been devised, OK'd—use whatever expression you want—by those person's charged with that responsibility within NIH but that now it has been put on hold until a commission is appointed and to ascertain those guidelines before we can move ahead in this area. Am I correct so far?

Dr. WYNGAARDEN. Yes.

Senator WEICKER. I'm just trying to paraphrase.

Now, over 1 year ago the Congress, by law, mandated a biomedical ethics committee, and I was the first chairman. And it is a rotating chairmanship. After 1 year, then somebody else comes on from the House, and so forth. So, I'm still a member of the committee, but no longer chairman.

The entire first year of the deliberations of this august body was spent in debating the prolife leanings of the various members of the advisory board which we were supposed to appoint. And the net result is we haven't done a darned thing.

Now, I want to know if we are going to get into this same quagmire insofar as the NIH is concerned while very promising research is being put on hold. If that is the case, a lot of people are going to go through needless suffering and/or loss of life out there while we get into this great debate which has bogged an entire Congress. Or are we going to go ahead and move forward in the sense of the decisions being made by men and women of science?

Now, how exactly is this going to play itself out? I gather the Assistant Secretary for Health is the one that ordered this thing be put on hold or a different route be traveled. Where do we stand on it? Exactly what are you doing to go ahead and get this matter resolved?

Dr. WYNGAARDEN. Your summary is essentially correct, Senator Weicker.

We intend to convene the committee that the Assistant Secretary requested, and we have been considering the structure and membership of that group. The present plan is to hold a meeting that might run for about 2½ days. The first day would be spent examining the scientific opportunities and potential for research and product development using human fetal tissue. There would be one-half day for public testimony, one-half day for the ethical considerations by a different component of the same panel, and then an evening and one-half day for writing a report.

We hope to convene the committee as soon as we possibly can. We think that we can have all of this pulled together within a week or two and can hold a meeting as soon as we can find an agreeable date for the members.

We think it is an urgent matter. We would like to get this accomplished in the shortest possible time consistent with meeting the quality objectives that we feel must be met, and see what the recommendations are.

Senator WEICKER. Now, in the meantime, is the use of such fetal tissue pretty much on hold across the country? As I understand, just within my own State, Yale University has been prominent in this area. Now, are they on hold also?

Dr. WYNGAARDEN. All investigators—both extramurally and intramurally—are on hold for any new procedures for the use of fetal tissue involved in human transplantation studies. That is the only component that is affected.

One scientist has done islet cell transplants in diabetic patients. It is the only case that we know of in which fetal tissue is being used in human transplantation, and he has voluntarily put any further accessions into his program on hold pending the results of the committee's recommendations.

Senator WEICKER. Am I correct in saying that the use of such tissue was approved within the NIH?

Dr. WYNGAARDEN. We have been following departmental guidelines, stating that such tissues can be used only when the scientist plays no role in the clinical decisions or in declaring when legal death occurs. No financial considerations may be involved in the use of fetal tissue. We are stringently following those guidelines.

In addition, all Federal, State, and local regulations must be met wherever such work takes place. We don't know of any infractions.

Knowing that this was a very sensitive issue, we have sought guidance from the Department. And after a number of discussions as to whether we should or should not proceed with the use of fetal brain cell implants in patients with Parkinson's, the present plan was handed down.

Senator WEICKER. Would many of the same considerations be involved as to the implant of fetal tissue as would be involved with any other organ transplant? Would many of the same considerations come into play?

Dr. WYNGAARDEN. No; these procedures would involve tissues obtained from elective abortion procedures. There is no moratorium on using fetal tissues from nonelective abortions. The problem is that those tissues are frequently not usable because the abortus may be too old and sterile conditions are hard to ensure. There is no controlling the timing of such procedures or such events. It really is a question of the use of tissues obtained from elective abortions that has brought this issue to the fore.

Senator WEICKER. And when do you expect a decision to be made? Again, you've given me a rough timeframe as to what you expect the commission to work within. What are we talking about as to what you would hope for in terms of guidelines so that that may proceed?

Dr. WYNGAARDEN. We are aiming for a date of 6 to 8 weeks, if we can meet that schedule.

Senator WEICKER. From now?

Dr. WYNGAARDEN. From the time the members are contacted.

Senator WEICKER. When do you expect the committee to——

Dr. WYNGAARDEN. We expect to have our planning done within a week or two.

Senator WEICKER. You are putting forth names?

Dr. WYNGAARDEN. Yes; we have solicited names from the community and from our Institutes, and we have quite a roster of impressive individuals from which to select.

Senator WEICKER. And then is somebody else also supplying names?

Dr. WYNGAARDEN. We have received suggestions from the neurological community and from the obstetrical community.

Senator WEICKER. I would certainly appreciate being kept informed in a very timely fashion as to how this thing is moving along.

Dr. WYNGAARDEN. We'll be happy to do that, Senator.

Senator WEICKER. Going from my own personal experience in this area, I have a strange feeling you and I might be sitting across this table 1 year from now without anything having been done. And that would be a great tragedy to the cause of medical science, research, whatever.

And maybe it is that this particular procedure doesn't hold promise. I'm not here to argue that. But at least the people who are in a position to know ought to have the opportunity to pass upon that, not a bunch of philosophers—well, I think enough said.

Dr. WYNGAARDEN. We agree, and we hope we can put together a committee that can really speak to these issues with scientific authority.

## TROPICAL DISEASES

Senator WEICKER. One last question. I have other questions I'm going to submit for the response for the record.

I remember when my good friend Dr. Krause used to be at Infectious Diseases, we spent a little time on malaria, and other types of infectious diseases, and also tropical diseases. With all the focus on AIDS, and a proper focus, nevertheless these other matters continue to move along. And I was wondering exactly what the status of our research in the tropical diseases is, and have we embarked on initiatives in this particular area?

Dr. WYNGAARDEN. We have recently surveyed the NIH effort in tropical and other exotic diseases, and have found that we have a very substantial array of projects in this field. It has been a field that doesn't have the same sort of constituency backing as, say, cancer and heart disease in this country.

Nevertheless, we feel that this is a very important area. I was interested in seeing the scope of our collective effort and also to what extent the modern tools of biomedical science have influenced these groups of diseases. I was pleased to find that there is some very high quality research making use of the latest recombinant methods, unraveling antigens from some of these organisms, and so on.

We are also aware, of course, that many other agencies such as the Defense Department and AID are very active in this field. We were interested in seeing what our collective effort is.

I know that many of our extramural advisors have taken the point of view that this is a very large and underaddressed area of particular diplomatic value to the United States. Should we be able to do even more, it would help these conditions in the Third World. We know there is progress going on, for example, on the Merck compound that is made available for river blindness. It represents a significant development that reflects high credit on the United States and on the pharmaceutical industry. I am curious as to whether we can do more that will lift the image of this country in terms of its initiatives to benefit mankind of the globe.

Senator WEICKER. Several years ago I thought we were within a cat's whisker of overcoming malaria. Where do we sit on that at this juncture?

Dr. WYNGAARDEN. About 3 or 4 years ago, we thought we were within about 1 year of an effective vaccine. In the later stage clinical trials, however, it didn't work very well. And so, it is back to the drawing board with that vaccine.

Dr. Fauci could speak to that more authoritatively, if you would like.

Senator WEICKER. Dr. Fauci, do you have a comment on this?

Dr. FAUCI. As is the case with many tropical diseases, the parasite itself is a very elusive microorganism; this is particularly true of malaria because there are so many stages in its life cycle. As it turned out, the vaccine was able to confer some very, very slight partial immune protection against the particular stage of the malaria life cycle to which it was directed; but the rest of the cycles broke through. So, as Dr. Wyngaarden said, it is really back to the drawing board.

There are still a lot of activities going on now using recombinant DNA technology to define and develop particular antigens of malaria. So, the research is still going along very actively with some important scientific advances. How that research will be translated into a practical malaria vaccine just remains to be seen.

Senator WEICKER. Has research at your Institute been impeded by virtue of concentration of effort by the Institute, certainly by you, on the matter of AIDS?

Dr. FAUCI. No; it has not because, as Dr. Wyngaarden said, in tropical medicine, for example, there has been a new resurgence of interest because of the particularly difficult problem that central Africa is having with AIDS. So, taking a look at the effect of the suppression of the immune response on a variety of other tropical diseases has renewed interest in those diseases and, in fact there has been some spurring of scientific activity in that area.

Senator WEICKER. Thank you very much, Mr. Chairman.

Other questions can be responded to for the record.

### FLORIDA DEMONSTRATION PROJECT

Senator WEICKER. Thank you.

Dr. Raub, when you testified last year, I asked you about the potential of the Florida demonstration project. I want to take this occasion to thank NIH and you for your initiative in this matter, and particularly thank you for your participation in the hearing that we held in Orlando last April with Florida officials. A lot of water has passed over the dam since last year. Vice President Bush and the administration have taken an interest in expanding the demonstration, and that is certainly good news.

I understand you recently reported to OMB in your capacity as chairman of the interagency group and put forth a plan to implement expansion of the demonstration.

How do we stand on moving forward with that, and how can we help give additional support from this committee?

Dr. RAUB. Mr. Chairman, I believe we are within a matter of days or a few weeks from having an OMB decision on the report.

As I believe you know, our interagency committee submitted a set of recommendations last January, and then we had a personal meeting with some senior OMB officials. The response was very encouraging, with a specific request that we address the details of implementation and provide a supplementary report. Within the last few weeks we provided that report.

We understand that it is seen as fully responsive to the OMB's request, and I'm optimistic that, with that reaction from the OMB staff, plus the recent ringing endorsement from Vice President Bush, we will soon be in a position of being able to do two things. One is to offer most of the features of the Florida demonstration project on a Governmentwide basis such that all R&D agencies would have the opportunity to employ them as they see appropriate in their research programs across the country; and, second, to be able to expand and continue the Florida project to involve institutions in other States and to deal with additional subject matter topics. We hope to involve other agencies of the Federal Government beyond the five charter participants.

Senator CHILES. How long would you see that expanded project taking? What do you see as the life cycle of that?

Dr. RAUB. In principle, it could be an indefinitely continuing effort based on the number of players and the subjects selected. My view would be to be very prudent in the beginning of the next phase and to identify two or three particular topics for further study and demonstrations that might be carried out within a timeframe of, say, 2 years so we can have continual scrutiny of the process, but also demonstrate that this effort is producing products that are not just study material, but are actually impacting across the whole system.

Senator CHILES. Well, if it is going to be ongoing—and that sounds like it might be a very good idea I think to put some milestones in there, again, of what you would expect to do, and like you say, don't add too much in there at one time so you can produce some product would be very valuable.

Dr. RAUB. I think you are quite right. I use the analogy of having a notch in the gun to demonstrate that the study has practical results in the whole grant system.

Senator CHILES. Well, I think one of the things I'm interested in is when can I start sort of touting the project to my colleagues here or to get them interested or showing them this is something that they should be interested in. I don't think there is much knowledge about it right now in the Congress.

Dr. RAUB. The optimist in me says this would be a good time to do that. I think there is a growing interest and acceptance.

Senator CHILES. I think that that needs to have the final approval of OMB and then a sort of go-ahead into the next phase to be able to do that properly.

Dr. RAUB. Indeed, it does. I agree.

Senator CHILES. Dr. Wyngaarden, we thank you very much for your overview presentation. I want to move on now to the Directors of the National Library of Medicine, the Fogarty International Center, the Division of Research Resources, and the National Center for Nursing Research. We would like Dr. Lindberg, Dr. Kupfer, Dr. Pickett, and Dr. Hinshaw to come up to the table. I would like each of you to give us a very brief statement, if you would, of your recent accomplishments and your proposals for 1989. Dr. Lindberg, we will start with you. Dr. Lindberg?

## NATIONAL LIBRARY OF MEDICINE

### OPENING STATEMENT

Dr. LINDBERG. Senator Chiles, Senator Weicker, it is a pleasure to come before you once again to talk about the National Library of Medicine.

This has been a good year for NLM. With the support of Congress, the growth of our collections and computerized data bases has continued. NLM remains the biggest biomedical library in the world. But beyond this and probably more importantly, we have found new ways to use computers to increase people's access to this wealth of information. I would like to mention two such developments during the last year.

First, special funds were provided 2 years ago by the Congress for the library to cooperate with universities and other organizations and begin to develop a unified medical language system. The first widely useful product of that research is Grateful Med. This is an inexpensive computer program that is sold to American doctors and other health care professionals to help them search the NLM files. I have brought along a copy of this program for you to see. It consists of an instruction book and two computer diskettes.

With that system, a physician with a personal computer, and without any special training, can access our data bases 24 hours a day, if he needs.

Senator CHILES. Now, does he have to have a special kind of computer?

Dr. LINDBERG. We designed this first version for IBM PC's of various sorts, and for the industry compatible clones. In other words, it covered at the time the majority of the market. We are now going to bring out a version also for Apple.

Senator CHILES. It was the majority of the market now.

Dr. LINDBERG. Yes.

Since it has been successful, we are now going to come up with a version that will cover another segment of the market, which is the Apple Co.

With this system, it is possible to get information literally within seconds at any time of the day, information that can be useful in the management of clinical problems.

Senator CHILES. How wide is it being accepted or used by the medical profession?

Dr. LINDBERG. Within 2 years of its introduction, Grateful Med has come to represent 36 percent of all the codes accessing the system.

Senator CHILES. So, 36 percent.

Dr. LINDBERG. In the past year we have seen an increased growth in participation by institutions and individuals.

Senator CHILES. That still doesn't tell me what percentage of the doctors. That is 36 percent of your inquiries.

Dr. LINDBERG. That is an elusive number. We estimate probably 10 percent. We are not sure. We are going to go after that figure. I would like to know that.

Senator CHILES. Has the fact that you have this information been widely distributed through the medical journals and the different specialties and all?

Dr. LINDBERG. We are doing the best that we can on that, but I would say, obviously, it is not as widely distributed as it should be. As you are aware, the latest authorizing legislation includes language that mandates NLM to publicize the availability of these services. We take that very seriously and are figuring out just how to do that in the best way.

Senator CHILES. I would certainly concur. I know we are spending some money on it. So, we ought to try to get it so it can be used.

Dr. LINDBERG. I feel exactly that way.

Senator CHILES. Obviously, this would be cheaper than your having to answer these inquiries in the old way—the other 64 percent.

Dr. LINDBERG. Yes, sir; even better than that, as a matter of fact. One composes the inquiry while he is just connected to his own computer and not online. So, we are not charging anything at that point. The user saves about 25 percent by using this system. The Government benefits also because it is saving additional computer power for other uses.

I think the approach takes advantage of the growth of the computer and telecommunications industries and also the increasing technical sophistication of American physicians.

We are confident that in the next 3 years we will be able to add developments from the unified medical language system to make the data bases even more accessible and useful.

There is a second major development that I would like to bring to your attention. That, too, is a result of a special congressional initiative; namely, that NLM was given funds to establish the National Center for Biotechnology Information, to participate in the informatics part of the human genome project. I might say that that was totally compatible with the long-range plan drafted by the Board of Regents and 120 outside consultants. This initiative has our 100 percent agreement as a top priority.

The center responds to the need for coordination and integration of information in the fields of molecular biology, biotechnology and the fast growing knowledge of the chemical sequences and mapping of the human genetic makeup.

During the past year we have accomplished the following things. One, we established the center as a branch in the Lister Hill Center.

Second, we joined with other NIH institutes to support and expand GenBank and certain other existing computer data systems.

Third, we have developed an advanced professional work station at NLM that allows scientists to examine and compare many different sources of biotechnology data at once. That is useful in discovery and research. We have worked to increase the compatibility between and among systems—our systems and those of other organizations.

We sponsored a number of symposia and workshops at NLM to share these developments.

Last, we have allocated $1 million this year to support research grant applications from universities and research corporations aimed at increasing the extent to which you can put biotechnology information in computers and use it to see new relationships and to aid discovery. This last week we completed review of the first 36 such applications, and they were of excellent quality.

These are just highlights. I'll be happy to answer any questions about these or remaining NLM activities. NLM's approved request is for $70,626,000. Thank you.

OUTREACH

Senator CHILES. Thank you.

Last year the committee provided additional authority by earmarking $1 million for the initiative of trying to publicize the availability of the latest scientific findings in the biotech field. What have you done in that regard?

Dr. LINDBERG. We have taken the first steps of our outreach program.

Senator CHILES. In biomedical information. You have told me about the genome, but what in addition to that?

Dr. LINDBERG. Yes, sir; we have discovered that through that kindness, we were able to increase the amount of publications, which the OMB will permit us to do, to publicize the information services of the library, and we have commenced to do that.

We have also commenced to represent ourselves at scientific meetings at an increased level which we think is appropriate, getting this information to clinicians where it needs to be.

In addition to that, we have increased our efforts with the regional medical library network to publicize the services that are available from NLM. They also provide training in advanced systems.

I should point out to you that the American medical libraries are good and are staffed with excellent people. They are probably a lot more technologically advanced than public librarians, for example. Particularly, the medical schools have more familiarity with networking in computers than most, but even they need to be brought in for advanced training. In their own educational programs in the universities, they are trying to revamp somewhat to include more advanced work in computer systems and networks.

One thing I should mention in connection with the outreach is NLM's system called Docline. That is a computer system that facilitates interlibrary loans. That is really at the heart of our expectation that a doctor anywhere in the United States would be able to request a copy of whatever journal or article he needs to take care of a patient. I mean, we have assumed all along that that is our goal. You don't have to be in Washington or Boston or New York. You can be anywhere and receive needed information. To get the journal article sometimes requires that it be sent, and Docline facilitates this capability.

Begun as an experimental system, Docline now has almost 1,600 major libraries participating in the system. We were encouraged by the funds that you gave allowing us to make the service a free one rather than forcing users to pay an additional amount to get this service. It is certainly an act in the public good. That is the only thing that can come out of it.

So, that has been very, very well received by the libraries, and I'm sure it is going to mean that we will get most of them on board. And as I said, we are doing exhibits to make sure that that is well-known.

Senator CHILES. Thank you.

Dr. Kupfer?

### JOHN E. FOGARTY INTERNATIONAL CENTER

Dr. KUPFER. Yes, sir; I'm serving as Acting Director of the Fogarty International Center, and have been in this position for approximately 4 months. It is quite clear to me that the Fogarty International Center is playing a very important role in international health, especially in terms of research training. We have very extensive fellowship programs with scientists from the United States going abroad, as well as scientists from abroad coming to the United States.

One of the major accomplishments last year was the hosting and coordination of the III International Conference on AIDS held in Washington, DC, and attended by an estimated 7,000 participants representing almost 100 countries. More than 1,000 scientific presentations contributed to the review and exchange of information on AIDS disease. The largest meeting that the Public Health Service ever hosted, this conference provided extensive new information about AIDS. We will also be partially supporting the IV International Conference on AIDS to be held in Stockholm this June.

I would like to comment on the fact that the Senate appropriated an additional $3.5 million to the Fogarty International Center for AIDS activities in fiscal year 1988. There have been extensive discussions with the Director of the National Institutes of Health, and the Directors of the National Institute of Allergy and Infectious Diseases, and the National Cancer Institute, as well as with the World Health Organization's AIDS program, in how best to deploy these resources. Discussions with the Fogarty Advisory Board have focused on trying to develop independent groups of researchers throughout the world who will be able to conduct surveillance activities for AIDS, and who will then be in a position to test new vaccines and antivirals throughout the world.

Proposals are coming in now for the support of training of postdoctoral fellows in AIDS epidemiology; we should know by the September board meeting of the Fogarty International Center how those funds will be used.

The Fogarty International Center requests a budget of $11,338,000 for fiscal year 1989. This does not include $4,736,000 for AIDS research and education presently being consolidated in the Office of the Assistant Secretary for Health.

I would be happy to answer any questions.

Senator WEICKER [presiding]. I have no questions at this time. Why don't we move along to Dr. Pickett?

## DIVISION OF RESEARCH RESOURCES

Dr. PICKETT. The Division of Research Resources undergirds biomedical research through six extramural programs.

The Clinical Research Program supports 78 general clinical research centers which provide specialized clinical resources and laboratory facilities for over 4,400 clinical investigations each year. Through the Clinical Associate Physicians Program 35 to 40 junior physician faculty members gain critical experience to enable them to become clinical investigators. Many important clinical studies are conducted in these centers. For example, the cystinosis study cited by Dr. Wyngaarden this morning was carried out in one of those centers.

The Biomedical Research Technology Program provides access to advanced technologies for biomedical researchers at 63 resource centers. This program focuses on biomedical computer resources, biomedical engineering, and instruments for the study of biological structure and function. We are active in the gene sequencing activity and in supporting software development for utilization of sequence data.

The Laboratory Animal Sciences and Primate Research Program provides resources for research involving animals, including the regional primate research centers, diagnostic laboratories, grants for the training of specialists in laboratory animal sciences, and grants that enable upgrading of laboratory animal facilities.

Furthermore, this program provides for the development of biological models and materials; such as invertebrates, lower animals, nonbiological systems, and cell and tissue culture systems which may reduce animal use.

The Biomedical Research Support Program enhances and strengthens the research capabilities of research intensive institutions. Approximately 635 such institutions will receive awards from the BRSG, the formula grant, in fiscal year 1989.

Also under this program activity is the Shared Instrumentation Grant Program. In 1989 we expect to award approximately 140 state-of-the-art laboratory instruments for use in biomedical research.

The final activity under the BRS Program is the Minority High School Student Research Apprentice Program which provides over 1,100 minority high school students with summer laboratory experiences each year at research-intensive institutions. The goal is to encourage them to pursue careers in biomedical research. Apparently we are not doing too badly. In 1988, 3 of our students, 1 each from California, Texas, and Wisconsin, were among the 40 winners of the Westinghouse science talent search.

The Minority Biomedical Research Support Program is a major component in NIH's efforts to increase the numbers of underrepresented minorities in biomedical research. We provide research support to institutions serving predominantly ethnic minorities. In 1989 we will award 98 grants which will support around 800 research projects, and research assistant positions for over 1,100 undergraduate students and 400 graduate students.

The DRR also administers another minority program, the Research Centers in Minority Institutions Program, which is funded through the Office of the Director of NIH. This program's mission is to enhance the research infrastructure at institutions heavily serving minorities that award doctorate degrees in the health professions and the health sciences. Fifteen such institutions are currently funded and are building their faculties, their libraries, and their equipment repertoire to develop a fuller role in biomedical research.

AIDS research takes place in at least 40 of our general clinical research centers, and all 7 of the primate centers provide investigators access to nonhuman primates for AIDS and AIDS-related research.

The sixth activity that we direct is a new AIDS program implemented as a result of congressional action on the 1988 appropriation. We call it the Research Facilities Improvement Program. The conference report referred to it as the AIDS infrastructure support. It is designed to provide 1-year awards for renovation, modernization, and expansion of facilities for AIDS research, along with the purchase of equipment associated with the facility improvement.

We are moving along quite rapidly with that program. Our request for applications is already out, as are our guidelines. We expect receipt of the applications on July 15, 1988. All awards will be made by December 1. We have had 350 telephone calls on the hotline set up for inquiries in response to an early alert sent out to the field. If even one-third of those people submit applications, we will easily expend the $23,935,000 that is available for that program.

Funds for AIDS research in 1989, as you know, are contained in the AIDS request for the Office of the Assistant Secretary for Health. However, no funds are included in the 1989 OASH request for the Research Facilities Improvement Program.

Just one other note. During the NIH centennial, which coincidentally was DRR's 25th anniversary, our organization sponsored a number of special events, including scientific symposia and workshops related to each of our major programs; including a jointly sponsored MBRS MARC symposium which was very well attended and, indeed, included a number of congressional participants from both House and Senate and staff; a lively minority high school student research apprentice workshop; a congressional breakfast, also very well attended, on advanced technology; a symposium on the benefits to animals and humans of research using animals; and clinical research symposia at several of our centers.

The request for the Division of Research Resources for 1989 is $319,977,000.

I will be pleased to answer your questions.

Senator Chiles [presiding]. Thank you. I'll wait and then ask you several questions.

Dr. Hinshaw?

## NATIONAL CENTER FOR NURSING RESEARCH

Dr. HINSHAW. Mr. Chairman, it is a privilege to address this subcommittee as the Director of the National Center for Nursing Research at NIH. We are proud to be the newest part of the National Institutes of Health, and it is a pleasure to discuss our programs and plans for the future.

I would like to highlight several areas of nursing's scientific endeavors which are revealing important information for patient care. One area concerns the adequacy of patients' oxygenation as affected by standard nursing procedures. A consortium of investigators is studying blood oxygen saturation during turning, positioning, back rubbing, and endotracheal suctioning. Study findings should provide us a basis for establishing procedures that minimize a patient's oxygen loss during administration of nursing care.

A second area of research yielding important results concerns urinary incontinence, a major health problem for the elderly. NCNR supports studies of behavior interventions including prompted voiding, biofeedback, pelvic muscle exercise, all of these to improve bladder control. These studies are being cosponsored and cofunded with the National Institute on Aging.

A third area of research is the critical field of low birth weight infants. One area of scientific investigation relates to evaluating the safety and effectiveness of followup home care by nurse specialists for low birth weight infants who are discharged early from the hospital. This type of home care appears to be as beneficial to the infant as extended hospitalization and certainly at significantly less cost.

In addition, NCNR has undertaken a number of initiatives addressing society's and the profession's concern with the nursing shortage. Support has been provided for a number of research project grants, fellowships, and career development awards relating to nursing resources and patient care delivery. These include, for example, studies of nurse retention in intensive care units and studies of drug use, stress, and job performance among nurses.

As a new and small enterprise at the NIH, the National Center must take special care to choose the best way to use its resources. Research training has emerged as one of the highest priorities in our discussions with leading nurse investigators, educators, and professional organizations. Therefore, the training recommendations of the National Academy of Sciences have been adopted, and in 1988 we have taken the first step toward this goal. In addition, a committee of leaders in nursing science is assisting the NCNR staff in defining a logical research training and career development trajectory.

Studying aspects of patient care in collaboration with other institutes is now a reality. The NCNR is cofunding or cosponsoring research projects, cooperative agreements and small business innovation research projects with several institutes. For collaborative career development, for example, qualified nurse investigators are being facilitated to conduct research within the general clinical research centers of the DRR of which Dr. Pickett just spoke.

The Center is also working to select the most promising subjects for future research emphasis. We have begun a 2-year planning process to define a national nursing research agenda. The first two priorities have been established. These are research on the nursing care of AIDS patients and research on the prevention and nursing care of low birth weight infants.

Mr. Chairman, the fiscal year 1989 budget request for the National Center for Nursing Research is $24,400,000.

I will be pleased to answer any questions.

### GORGAS MEMORIAL INSTITUTE

Senator CHILES. Thank you very much.

Let's go back now to Dr. Kupfer. Last year the committee provided $1,934,000 for the Gorgas Memorial Institute in Panama. The Institute has been criticized in recent years, and NIH, we are told, considers the funding provided for Gorgas simply as a passthrough. In other words, a limited amount of oversight is provided. Additionally, we know the National Institute of Allergy and Infectious Diseases has a Division of Tropical Medicine.

Is Gorgas Institute, which was created in 1928, something that now should be competed every so many years, and is its existence in Panama important from a truly scientific perspective?

Dr. KUPFER. Senator, perhaps I could defer responding to the first part of that question because it really would depend upon an intimate knowledge of the Gorgas Memorial Institute in terms of its overall management and scientific activities. The Fogarty International Center serves as a conduit for the core support that is appropriated annually by the U.S. Congress, but has no responsibility or authority for management of the programs at the Gorgas Memorial Laboratory.

Senator CHILES. So, if you are just the passthrough, who does oversight of it?

Dr. KUPFER. That's a very appropriate question. Perhaps I could clarify the situation by referring to a letter from the Comptroller General of the United States dated September 1980 in which it is stated that, "The appropriation to the institute"—that is, Gorgas—"is in the nature of an outright, unrestricted gift. Consequently, the usual restrictions applicable to grants do not apply." This is really the situation that exists at the present time.

There is oversight at Gorgas by an external review group that the leadership of Gorgas has identified. But as far as oversight by the Fogarty International Center, or by any other element of the National Institutes of Health, that is not at present in place.

Senator CHILES. So, this is just a gift that we have set up. It is $2 million a year now. And you don't do any oversight. You're just the passthrough. You're the conduit.

Dr. KUPFER. Yes, sir; there has been, of course, interest in activities of the laboratory. In reference to the second part of your question, there is the perception that Gorgas is a very important research facility in Central America that has a major role to play in studying tropical diseases and other diseases that exist in Central America, and throughout Latin America.

As a result, there has been interest upon the part of the Fogarty Advisory Board to make informal site visits to Gorgas and to observe ongoing research activities. As a matter of fact, in January the Director of Gorgas, Dr. Reeves, made a scientific presentation to the Fogarty Advisory Board, which was extremely well-received.

Senator CHILES. What is the budget of the Gorgas Institute?

Dr. KUPFER. The U.S. contribution was $1,934,000 in fiscal year 1987.

Senator CHILES. I know what that is, but what percentage of their funding is it?

Dr. KUPFER. The overall total for 1987, was $3.122 million. In addition to the United States contribution, funding that is passed through the Fogarty, there is funding from other NIH components consisting of grants and contracts, from other elements of the Government, from Panama itself, and from the World Health Organization and the Pan American Health Organization. They do have a consortium providing research resources.

Senator CHILES. If two-thirds of it is coming through you and then there is other money from NIH that is going in there——

Dr. KUPFER. But the other NIH money is peer reviewed. In other words, these are requests in the usual manner for research grants, or for contracts that are peer reviewed.

Senator CHILES. Well, for the record, give me a breakdown of where their money comes from.

Dr. KUPFER. I'd be happy to, sir.

Senator CHILES. I'd like to see that.

Dr. KUPFER. Certainly.

[The information follows:]

### OTHER SOURCES OF SUPPORT FOR THE GORGAS MEMORIAL LABORATORY

In fiscal year 1987, other than the United States contributoin of $1,934,000, the GML received a $10,000 contribution from the Government of Panama and the following support for peer-reviewed projects:

| | |
|---|---|
| Other NIH: | |
| Studies on the maintenance mechanism of Gamboa virus (grant from NIAID) | $61,630 |
| Epidemiology of HTLV-1 in Panama (contract from NCI) | 153,231 |
| Epidemiology of cervical cancer in Latin America (contract from NCI) | 425,964 |
| Human papillomavirus and cervical cancer in Panama (grant from NCI) | 120,152 |
| Other U.S. Government: | |
| Medicine in the tropics (training course for naval officers from U.S. Navy) | 104,386 |
| Drug evaluation in the plasmodium falciparum-aotus model (contract from U.S. Army) | 123,674 |
| Pilot study of the efficacy and safety of ketaconazole in the treatment of cutaneous leishmaniasis (contract from U.S. Army) | 24,894 |

| | |
|---|---|
| Other United States: | |
| Prospective study of the transmission of toxoplasmosis in Panama (subcontract from the University of Kansas Medical Center which is funded by NIAID) | $153,231 |
| Environmental protection of Maje Island scientific reserve (from Food and Health Foundation, Boston) | 2,901 |
| Other: Pilot evaluation of vaccines against cutaneous leishmaniasis in the night monkeys (WHO/PAHO) | 14,605 |

Also, from a $20,000 donation from the estate of Elena Maduro Fidanque, the GML is conducting a clinical study of infections in newborns. In fiscal year 1987, $982 was spent on this project.

### AIDS

Senator Chiles. Last year the committee gave the Center $3.5 million for AIDS. This increased the Center's funding by 30 percent. In providing this funding, the committee indicated that an effort should be initiated to prepare for coordinated vaccine trials on an international basis.

How have these funds been used?

Dr. Kupfer. These funds are being directed toward developing a research base that would be able to respond to trials of new vaccines and new antivirals throughout the world. We are doing this in a number of different ways. First of all, we are looking into what other institutes at the NIH are funding both domestically and projects having a foreign component, especially in the case of the National Institute of Allergy and Infectious Diseases. We hope to use some of the Fogarty funds to support the foreign element of these research grants from the Institute of Allergy and Infectious Diseases, the ICAR programs.

In addition, we are supporting postdoctoral research training in AIDS and epidemiologic training in AIDS so that there will be the capability throughout the world to have units in place to do the drug and vaccine testing and the surveillance.

Some of the funds, approximately $100,000, are being used to support U.S. scientists who are making presentations at the IV International Conference on AIDS. But the main thrust will be in research training.

### INTERNATIONAL FELLOWSHIP AWARDS

Senator Chiles. Since the International Fellowship Research Program began in 1958, some 2,500 awards have been made, and 54 percent of those were made to scientists from European countries, 20 percent from Asian, and 17 from the Americas, and the balance from the Middle East and African.

Is it necessary to continue having the largest majority of these scientists being awarded to western Europeans?

Dr. Kupfer. This is a very appropriate question and, as a matter of fact, the Fogarty Board is currently going through a program planning exercise and this is one of the considerations that is being discussed in great detail. I hope the new Director of Fogarty, when appearing next year before the committee, will be able to respond specifically to this question, because by then some new guidelines will be developed.

Senator CHILES. This year?

Dr. KUPFER. They will be developed this year, and I'm sure you will hear about them at the hearings next year.

Senator CHILES. Well, I don't think I'll hear about them. [Laughter.] You better move those up a little bit.

I may hear about them, but indirectly.

Dr. KUPFER. We would be glad to provide that information to you wherever you will be, sir.

### EXTRAMURAL FACILITIES FOR AIDS RESEARCH

Senator CHILES. Thank you.

Dr. Pickett, the committee provided the Division of Research Resources with about $24 million to be provided to extramural facilities around the country for AIDS research facilities. I understand you expect to make awards of this money before the end of the calendar year with applications due in by July 15.

What guidelines have you established to help ensure this money is fairly distributed to the areas of highest need, and have you established a maximum award level?

Dr. PICKETT. Yes.

Senator CHILES. And do you require a match?

Dr. PICKETT. We do not require a match. We have established the maximum award level at $1 million. We have also established a minimum award level of $250,000.

We have developed detailed guidelines for the two types of awards to be made under this program. We have special guidelines which utilize construction language, and we will use a construction grant application form for the expansion part of the program, and a version of the alteration and renovation guidelines for the remainder.

This program is a competitive program. A special review committee will be established to review these applications. This review is currently scheduled for the first week in September 1988. Applications will be given a second level of review by the National Advisory Research Resources Council which will meet in a special session on the October 31, 1988. To summarize, these awards will be subject to competitive review, will range from $250,000 to $1 million, with no matching requirement.

### ALTERNATIVES TO THE USE OF ANIMALS

Senator CHILES. Approximately 26 percent of all NIH research involves no live animals. About 41 percent involves animals. Nevertheless, there is a strong interest to have NIH develop alternatives to the use of animals in research.

Describe to the committee your plans to develop alternatives to the use of animals in research and what progress we can expect in that.

Dr. PICKETT. In the preceding calendar year, DRR established a study group to develop a plan for use of alternatives, and to publish a program announcement which indicated our interest in accepting applications on those topics. All of that was done. The first group of applications was received, and awards have been made. The announcement was reissued this February and we expect another round of applications to come in.

All of the institutes at NIH participated with us in the development of the plan, in the preparation of the announcement, and in the funding of the applications that were received in response to the original announcement. They have also been advised of the need to republish the announcement, which has gone out with input from all of the original planning group.

### NURSING SHORTAGE

Senator CHILES. Dr. Hinshaw, there is some indication that the current shortage of nurses is a more serious problem than previous cyclical shortages that have occurred earlier in the decade. Looking at the downturn in enrollment and the fact that patients in hospitals are sicker and, therefore, requiring more intensive stays, it certainly adds to the stress and makes the nurse's job less appealing.

Additionally, hospitals in an effort to hold down costs are adopting various personnel policies that don't encourage nurse retention.

Tell the committee what you have learned about the nursing shortage. Do you believe it is a normal, cyclical adjustment that will be self-correcting?

Dr. HINSHAW. If I may speak, sir, from some of the work that I have heard reported by the witnesses before the Commission on Nursing of which I am an ex officio member, it is apparent that the community views the present shortage as different than the shortages in the past years. This shortage may be more chronic in nature for several reasons.

One, we do seem to have a possible downturn in enrollments of students entering our schools of nursing. We also are looking at an economic set of conditions in terms of wages and the problem of compressed wages. The other issue is not concerned just with wages, but also with building professional practice environments in which nurses would feel comfortable and satisfied and be able to provided a quality of care which is the standard for them. I think all of these factors lead to the fact that we may, given also the increased demand that seems to be apparent, be looking at a longer, more chronic shortage.

Senator CHILES. Well, what should we be doing about it? You're the research arm.

Dr. HINSHAW. Several things have been undertaken. We have cosponsored two conferences in this past year with the Division of Nursing at HRSA because the Division of Nursing is responsible for the manpower and the educational aspects of the particular nursing shortage issue.

In those conferences we have looked at what the research is showing us at this point in time, what is usable, and what can those findings tell us. We have taken the findings both to the Commission on Nursing for the set of action recommendations that will be coming from that group, and also have evolved two particular initiatives at the Center.

One is a program announcement calling for further research because it is clear that while we are able to pinpoint the factors that retain or push nurses out of the different health care settings, that we do not have research yet on the definitive strategies given that basic research which will retain them within the system.

The second initiative is a cooperative agreement announcement, released April 15, that we are issuing with the Division of Nursing to support research on innovative practice models. Together, we are interested in demonstration and research projects that would build professional practice environments utilizing multiple strategies to retain nurses within these various health care settings and evaluating the effectiveness of those strategies.

### LOW BIRTH WEIGHT/INFANT MORTALITY

Senator CHILES. I note that you said one of your areas of research was looking at low birth weight babies. How are you looking at that problem and infant mortality?

Dr. HINSHAW. Well, we are particularly concerned from several viewpoints. One is nurses work a lot with adolescents through the school nursing and office nursing kind of arenas. In that regard, we have an opportunity to look at healthy kinds of behaviors, such as not smoking, drinking, or getting into early sexual behaviors for a high-risk population—that is, adolescent young women.

Nurses also work extensively in prenatal clinics and in the health care field in terms of home care. One of our research projects examined the ability to take the intensive care neonate home early, and found that those youngsters going home approximately 1 month early can be followed by nursing specialists in the field with home visits and phone contacts. Several significant benefits resulted. The relationship between the parents and the child begins to develop much faster. There is a great deal of satisfaction with having that child home. The early research suggests there may be fewer complications because they are not in the hospital in what could be conditions conducive to infections. And the cost of the neonate's health care would be reduced.

So, we'll be looking at these problems at different places, both in terms of prevention and the nursing care within the nurseries, and then the ability to take these children home earlier from the hospital.

Senator CHILES. Well, when we look at prevention, we know that one of our problems is low birth weight, of course. These young, pregnant, expectant mothers don't know that they shouldn't be smoking, that they shouldn't be using alcohol, they shouldn't be using drugs, and that they ought to be eating properly. And that has probably as much to do with that birth weight as anything.

Dr. HINSHAW. Exactly.

Senator CHILES. How can nurses help in that?

Dr. HINSHAW. Well, that is one of the areas that we would like to target. We currently have an investigator from Johns Hopkins working in that field. She is surveying 15,000 adolescents in the Maryland area trying to investigate what promotes healthy behaviors. For example, what stops young people from smoking and what keeps them from drinking early, what keeps them from getting into early sexual patterns that are not healthy. We need to describe those behaviors so that we can then put together some strategies for trying to promote them consistently and systematically in other young people.

### INSOMNIA

Senator CHILES. I noticed one of the other research projects was studying the insomnia patterns or sleeping patterns of patients in hospitals.

Dr. HINSHAW. Yes.

Senator CHILES. I'm not an expert on this. I have been in the hospital just several times, but my insomnia came from the fact that nurses woke me up. [Laughter.]

Dr. HINSHAW. I think your point is well made, Senator.

But I think also there are other factors that contribute to that.

Senator CHILES. I had to go home to rest.

Dr. HINSHAW. I'm sure that is true. But what we need to look at is what kind of factors effect sleep patterns and develop interventions which promote healthy sleep.

### CONSTRUCTION OF NURSING FACILITIES

Senator CHILES. Senator Inouye is very interested in extramural nursing construction needs. What are your informal estimates of the need here?

Dr. HINSHAW. I believe that last time the construction facility moneys were available for schools of nursing of any type was in about 1978. Those funds, under HRSA authority, were always targeted to educational and classroom facilities. There has not been funding for construction facilities targeted to research per se.

At the recent ad hoc committee for extramural construction facilities for NIH in general, there was testimony given by individuals from the American Association of Colleges of Nursing. They were testifying to the need for nursing research facilities since those moneys have not been available before. Possible uses for such construction funds include the addition of a wing or another floor onto a building, the alteration and renovation of current facilities, or in the long run, purchase of equipment.

Based on the early experience of the National Eye Institute, I would think that an early program such as that would not run less than $3 million in the first year.

## AIDS RESEARCH CENTERS

Senator CHILES. The committee understands that there are discussions underway as to whether or not the National Center for Nursing Research should establish a center for the care of AIDS patients. Give us an update on the status of that. And does your 1989 request include funding for a new center?

Dr. HINSHAW. No; the 1989 request does not. There have been some questions posed to us both in the House Appropriations Committee and now by yourself about a possible centers program. If we were to initiate a centers program, I think our first concern must be that it would not detract from the growth of our current research support and research training mechanisms for individuals in the field. If centers were to be considered, our preference would be for core centers organized around a clinical issue such as nursing care for the AIDS patient and family. That type of center could be established for nursing care of AIDS patients. Examples would be the physical care regimes such as skin care, mouth care, and handling of fatigue. The research could also include helping those individuals to stay independent and maintain self-care as long as possible. So, it would probably have an acute care home care and community health component as well, Senator.

Senator CHILES. Well, if you did anything like that, that care should look at the infant AIDS victims because that is one of our greatest problems, this boarder problem that we now have where mothers are abandoning their babies because they can't or are afraid they can't take care of them, and they are just leaving them in the hospitals where the cost, of course, is tremendous.

Dr. HINSHAW. Exactly. I would not see controlling the age span for such a center. I mean, it would cross different ages.

Senator CHILES. Well, we thank you.

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There will be some additional questions which we will submit to you for your response.

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## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### RADIOLOGY AND DIAGNOSTIC IMAGING

Question. Dr. Wyngaarden, we hear a lot about the promising new technologies that are helping us understand cancer, heart disease, arthritis, and Alzheimer's disease. Much of what we hear involves new developments in the field of radiology. But as far as I can tell, most of the Institutes have no specific radiology programs. How much of the NIH budget is devoted to research on radiology and diagnostic imaging?

Answer. During FY 1987, the NIH expended $58.1 million to support research related to improving or perfecting diagnostic imaging techniques. It is estimated that $61.1 million and $70.6 million will be awarded to support this effort in FY 1988 and FY 1989, respectively.

Question. How many training slots are devoted to this particular discipline?

Answer. The NIH currently supports five postdoctoral research trainees in the field of diagnostic radiology. Because diagnostic radiology has traditionally been a predominantly service-oriented discipline, it is difficult to attract well-qualified applicants to training opportunities in this field.

Question. Diagnostic imaging cuts across so many Institutes. Do you have a way of coordinating the research that goes on here?

Answer. This research is coordinated by the NIH Inter-Institute Diagnostic Imaging Group, which includes representatives from the National Cancer Institute, the National Institute of Dental Research, the National Institute of Environmental Health Sciences, the National Heart, Lung, and Blood Institute, the National Institute of Neurological and Communicative Disorders and Stroke, the Division of Research Resources, the Division of Research Grants, and the Clinical Center.

Question. Do you make it a practice to include radiologists on the advisory boards of the various Institutes?

Answer. The NIH components involved with diagnostic imaging research attempt to include such expertise on advisory boards, councils, and review committees.

Question. For the record, tell us how many radiologists are currently on all of the Institute advisory boards?

Answer. We have conducted a review of the membership of each of NIH's 14 national advisory councils and have found that no diagnostic radiologists are currently serving. The membership of councils reflects the authorizing legislation and the broad program areas of each Institute. The NIH recognizes the important contributions made by radiology research scientists and will seek qualified candidates for the councils advisory to those Institutes involved in diagnostic radiology research.

## SLEEP RESEARCH

Question. Dr. Wyngaarden, we are very interested in the activities of the Trans-NIH Sleep Research Coordinating Committee. Can you please advise us of the progress made by the Committee to enhance the overall NIH effort in basic sleep research?

Answer. The Trans-NIH Sleep Research Coordinating Committee has surveyed the sleep and sleep-related research portfolios of member Institutes to determine the level of such research at the NIH and has forwarded its report to the Congress. The Committee is also assessing the adequacy of peer review for sleep-related research applications. In late September 1987, the Coordinating Committee held a public meeting attended by representatives of the advisory councils of the member Institutes, staff from NIH, and members of lay organizations and professional sleep research societies. As a result of this meeting, member Institutes are considering additional program initiatives in areas of sleep research related to specific Institute missions.

Question. What additional activity could take place to enhance this effort even further?

Answer. We would be able to increase our support if members of the extramural sleep research community were to submit additional meritorious research project grant applications. Participating Institutes are taking steps to advise the research community of our interest in this area.

Question. Would it be possible for the Trans-NIH Coordinating Committee on Sleep Research to begin to serve in an advisory capacity to the NIH and Congress, similar to that of other advisory boards? If not, how could this be accomplished? Could sleep research experts from around the Nation serve on the Coordinating Committee in an ex-officio capacity?

Answer. The trans-NIH Coordinating Committee on Sleep Research is composed solely of Federal employees and therefore cannot function as a national advisory board. Such a board on sleep research could be established; however, this action would require DHHS approval and availability of funds to support the staff and the activities of the board. The present structure of the Committee allows it to solicit, on an ad hoc basis, the opinions of outside experts as needed.

## RESEARCH FACILITIES

Question. Dr. Wyngaarden, as you know, there is an interest in the university community for a new and continuing program to provide Federal funding for university research facilities. We received the report you forwarded to us from the Extramural Facilities Task Force, which recommended a $100 million program for FY 1989.

Each of the NIH grants includes funds for indirect costs, and the cost for buildings is specifically included as an allowable indirect cost. As you know, OMB Circular A-21 permits 2 percent of replacement building costs to be included each year as an indirect cost item. The 2-percent figure would reimburse an institution over a 50-year period for the cost of its buildings.

What consideration has been given to increasing this indirect cost rate to permit universities and other institutions to recover their building costs in a faster period of time?

Answer. The Extramural Facilities Task Force recommended increasing the Indirect Cost Use Allowance from 2 to 5 percent to allow an institution to depreciate facilities over 20 years rather than the current 50-year period.

Question. Have you considered this as an alternative to a new extramural facilities program?

Answer. In the opinion of the Task Force, an adequate facilities construction program would require a mix of both equity and debt financing. The Task Force did not address the offsets that would be required against other public health funding, however. Equity financing would be in the form of matching grants, and debt financing would be principally through the Indirect Cost Use Allowance. A change in the use allowance would be an integral part of a new research facilities construction program.

The Indirect Cost Use Allowance would provide enough funds for construction to those institutions with a large base of longstanding grant support. Emerging institutions, despite a strong commitment to research, would less likely be able to take advantage of this change. The Task Force therefore considered it important to have both equity and debt financing approaches for construction.

## SUPPORT OF RESEARCH GRANTS

Question. The FY 1989 request would support a total of 21,145 research project grants, compared with the FY 1988 total of 20,145. Of these, 545 would would be AIDS grants and 20,600 would be in non-AIDS research areas.

In the competing grants mechanism, however, the FY 1989 total is considerably lower than FY 1988. New and competing AIDS grants would number 150, compared with 187 in FY 1988, and there would be 5,611 non-AIDS competing grants compared with 5,865 in FY 1988. The totals for competing research project grants would therefore be 5,761 for FY 1989 compared with 6,052 for FY 1988. This FY 1989 total is much lower than the number of competing grants awarded by NIH in each of the last 4 fiscal years.

What effect will this lowered availability of research project grants have on paylines, award rates, and on young researchers' perceptions of the stability of NIH grant support?

Answer. First of all, one should keep in mind that total funding for the NIH, excluding AIDS, is proposed to increase by 5.4 percent. Any allocation among research mechanisms should be viewed against that background. In the FY 1989 request for competing research project grants including AIDS, the payline is 160 and the award rate is 31.7 percent. In comparison, the paylines and award rates from the previous 4 years are the following:

| FY | Payline | Award Rate |
|---|---|---|
| 1985 | 172 | 37.3% |
| 1986 | 171 | 36.1 |
| 1987 | 174 | 38.3 |
| 1988 estimate | 160 | 33.8 |

There may be some temporary impact on young investigators' perceptions of stability; however, if research project grants are viewed in totality, in 1989 we will support the highest number of grants in our history. This should strongly signal the Federal government's commitment to research.

Question. What savings are assumed from downward negotiation of grant costs?

Answer. Approximately $408 million would be saved based on the downward negotiations proposed in the FY 1989 budget for research project grants including AIDS (after historical downward negotiations). If downward negotiations in research centers and other research grants are included, the savings would be approximately $497 million.

Question. What level of downward negotiations will be required in FY 1989?

Answer. For noncompeting and competing research project grants, including AIDS, the downward negotiations would be about 9.5 and 13.0 percent, respectively.

Question. What effect will this have on research?

Answer. We anticipate some reduction in the scope of our research.

## SUPPORT OF AIDS GRANTS

Question. Support of AIDS grants would go from $140.5 million and 422 grants in FY 1988 to $239.2 million and 545 grants in FY 1989. However, competing grants would be $8.86 million (37 grants) lower in FY 1989. Is this the right time to scale back on support of new AIDS Research?

Answer. The total NIH AIDS request for FY 1989 is $587.6 million, an increase of nearly $120 million or 26 percent over the FY 1988 level. The majority of that increase is in basic research supported through research project grants and conducted in our intramural programs. Although the estimated number of new grants may be decreasing slightly, it is clear that our request does not reflect a reduced effort overall.

Question. The average cost of the AIDS FY 1989 noncompeting grants has risen 40.7 percent over the FY 1988 average--from $335.7 thousand to $472.2 thousand. What accounts for this large increase in the average cost of AIDS continuation grants?

Answer. The large increase in the average cost from FY 1988 to FY 1989 for AIDS noncompeting grants is due primarily to the conversion of the AIDS Treatment Evaluation Units (ATEUs) from the contract mechanism to the noncompeting research project grant mechanism. There are 18 ATEUs with an average cost per award of approximately $2.2 million. This, coupled with the continuation costs of initiatives implemented in FY 1989 which have high average costs per award (e.g., the 12 Programs of Excellence in Basic Research in AIDS have an average cost of $1.2 million) results in the large increase in average cost in FY 1989.

Question. Please explain the large discrepancy in average costs for FY 1989 competing grants between AIDS grants ($351.2 thousand) and non-AIDS grants ($181.4 thousand), and the even larger discrepancy for FY 1989 noncompeting grants--$472.2 thousand for AIDS grants and $191.1 thousand for non-AIDS. What factors make AIDS research so much more expensive?

Answer. Many of the AIDS initiatives have extremely high average costs that distort the overall picture. For example, the ATEUs cost approximately $2.2 million each, and, in the new targeted antiviral program, large program project awards are made at nearly $1 million each. Since the number of AIDS awards is relatively small in comparison to the non-AIDS program, high costs for individual programs have greater impact on average costs.

## SPENDING ON AIDS

Question. In its 1986 report Confronting AIDS, the Institute of Medicine recommended that research appropriations be increased "toward a level of $1 billion annually by 1990", and that "by 1990 there be significant federal contributions toward the $1 billion annually required for the total costs of education and public health measures." How does the AIDS effort contemplated for FY 1989 compare with that envisioned by the Institute of Medicine?

Answer. The IOM report did not specifically address a dollar level for FY 1989; therefore, we have no accurate basis for comparison. The $587 million that would be available at the request level is a 26-percent increase over the previous year and indicates a strong commitment to the AIDS effort.

## AIDS GRANT APPLICATIONS

Question. The conference report on the FY 1988 continuing resolution directed NIH to speed up the processing of grant applications for AIDS research from the usual average of 12 months to 6 months. How are you handling the new requirement to process AIDS grant applications within 6 months?

Answer. The NIH assigned approximately 20 senior staff to examine the estimated 10,000 unsolicited applications received for scientific merit review at the spring round of initial review groups. They identified 187 applications dealing with AIDS research. An additional 170 applications responded to special Requests for Applications (RFA). Virtually all AIDS grant application reviews were accomplished in late April by special ad hoc peer review groups. To accommodate especially large numbers of RFA applications, the NIAID conducted preliminary peer review triage procedures to identify those applications deemed worthy of further consideration in each competition. Plans call for all AIDS summary statements to be completed by early June, in time for Institute advisory councils/boards to conduct second-level reviews by July, allowing successful applications to be funded during August; i.e., within 6 months following receipt.

Question. What difficulties is this effort causing for the rest of your grant review system?

Answer. These special application handling processes have been accomplished by using available resources, but somewhat at the sacrifice of other activities. The very labor-intensive procedures require shifting incumbent professional and support personnel to special AIDS application receipt-review-award responsibilities. While the additional review meetings required are being handled by new staff recruited to meet the requirements for award within 6 months, related preliminary reviews of incoming applications and pre-award checks, approvals, and negotiations of grant awards also require special handling to ensure timeliness. This reflects the high priority of AIDS and accelerated AIDS grant reviews.

## COORDINATION OF AIDS EFFORTS

Question. Please describe the functions of the various coordinating committees, advisory bodies, task forces, etc. that NIH has established to guide the research effort on AIDS.

Answer. The Office of AIDS Research was recently established in the Office of the Director, NIH, to expand the role and staff of the NIH AIDS Coordinator position that was created in 1986. Dr. Anthony S. Fauci, in addition to his role as Director of NIAID, serves as Associate Director for AIDS Research, NIH, and heads this new office.

The NIH AIDS Executive Committee provides guidance and direction for NIH-wide scientific, planning, and resource allocation decision-making, and it facilitates effective coordination of efforts. The membership of the committee includes representatives from each of the NIH components involved in AIDS research, as well as principal staff from the Office of the Director, NIH. The committee also links the activities of NIH with other components of the PHS through the PHS Executive Task Force on AIDS.

The AIDS Program Advisory Committee is chaired by the Director, NIH. The members, who are selected by the DHHS Secretary, include nine individuals knowledgeable in the biomedical science and clinical care fields related to AIDS research, as well as four representatives of the general public. The purpose of the Advisory Committee is to advise the NIH on all aspects of AIDS research, identifying opportunities for further research and recommending initiatives that should be undertaken to advance knowledge in the diagnosis, prevention, and treatment of AIDS.

Other advisory groups exist in a number of Institutes to provide coordination in areas relevant to AIDS research. These include: (1) Institute advisory councils (NIAID and NCI have established specific AIDS subcommittees); (2) technical review committees; and (3) ad hoc advisory groups on specific issues/topics.

NIH intramural research activities are coordinated through a number of bodies, including the NIH AIDS Executive Committee, the NIH Scientific Vaccine Development Committee, the Intramural Targeted Antiviral Development Program, the DCT Decision Network Committee, the AIDS Clinical Drug Development Committee, the NIH Bimonthly AIDS Science Report, as well as the respective Institutes' Boards of Scientific Counselors.

Question. What similar bodies exist in PHS, DHHS, or elsewhere, and how does NIH interact with them?

Answer. The PHS Executive Task Force on AIDS is the major coordinating and focal point for all PHS and DHHS AIDS activities. Attendees at the bi-weekly meetings include representatives/staff of the PHS agencies and the OASH. The mission of the group is to exchange information and coordinate AIDS activities among PHS agencies, provide a forum for achieving consensus on AIDS issues, and develop operating strategies for PHS AIDS activities. As one of five agencies comprising the PHS, NIH participates as an active member of the group. There is direct representation of several NIH Institutes at the meetings, and the proceedings/informational items from the meetings are reviewed with the NIH AIDS Executive Committee in meetings coordinated to occur in the afternoon following the morning PHS meeting.

To facilitate improved communication and collaboration throughout the Federal Government, the PHS established a Federal Coordinating Committee on AIDS Education and Risk Reduction. The Committee is composed of seven Federal Departments (USDA, DOD, DOED, HUD, DOJ, DOL, and DOS), six independent agencies (Action, AID, EPA, OPM, USIA, and VA), and three offices within the Executive Office of the President (OMB, OSTP, and DPC). The committee is responsible for identifying government-wide issues,information/research/resource needs and gaps, and appropriate goals in the effort to combat AIDS.

The NIH has an active interest in close coordination with the international health research community in global efforts to combat AIDS. At the present time, the NIH has collaborative/coordinating activities with groups such as the World Health Organization (WHO) and the Pan American Health Organization (PAHO).

## TRANSMISSION OF THE AIDS VIRUS

Question. In their new book, Crisis: Heterosexual Behavior in the Age of AIDS, William Masters and Virginia Johnson cite a number of theoretical methods by which the AIDS virus could be transmitted. Could you please comment on the validity of their observations and on the Master and Johnson study in general?

Answer. In their book, Masters and Johnson (and Kolodny) speculate at length about the possibility that AIDS can be transmitted by contact with toilet seats or blood-contaminated food, by mosquitoes, or by contact sports. Although they admit that such routes of transmission are only theoretical, they make the point that we cannot scientifically rule out any of these possibilities. The authors then conclude that these are important routes of infection that have been downplayed by "benevolent deception" within the scientific community. Fortunately, speculation is no substitute for facts, and the facts speak much more forcefully than hypothetical scenarios.

If AIDS were transmitted by any of the routes cited by Masters and Johnson, the pattern of disease would be very different from that shown by all the data we have. Instead of a disease focused on homosexuals and intravenous drug abusers, we would see a disease, such as influenza, that has no clearly associated high-risk behavior. Therefore, whatever the theoretical possibilities of transmission by the routes that Masters and Johnson cite, we can definitely say that these are not important concerns, and they certainly do not require a panic response from the general public.

In general, the Masters and Johnson study is not a useful addition to the work on AIDS. Most of the data they discuss are either incorrect or outdated. Their own study of 800 heterosexuals is seriously flawed from epidemiologic, patient selection, and study design bases, and their conclusions can in no way be generalized to the population as a whole. For example, in their group of 400 subjects who had at least six different sex partners a year during the study, Masters and Johnson found that 5 percent of the men and 7 percent of the women tested positive for exposure to the AIDS virus. The Red Cross tested 8.8 million blood donors and found a rate of 0.2 percent, and the Defense Department tested 4 million military recruits and found a rate of 0.15 percent. The relevant issue is which of these two sets of data has the most relevance to the general population.

The burden of proof lies with Master and Johnson, not with the scientific community at large.

Question. What do you think are the responsibilities of scientists to the general public when explaining medical risks that are either very small or only theoretical?

Answer. Scientists have an important responsibility to the general public in this regard. Unfortunately, we do not really understand how best to convey this information. In the case of AIDS, we can say that the risk of getting infected by routes other than the well-described, high-risk activities is extremely low, although we cannot quantify the exact risk. Is it better to say that you have a 1 in 40,000 chance of getting AIDS from a blood transfusion, or that the risk of getting AIDS from 1 unit of blood is less than the risk of serious injury and death in driving from your home to the hospital to receive the unit of blood? Different people respond to such "relative risk" information in different ways.

We as scientists need to define risk when we can, make educated guesses when we cannot be sure, and admit our ignorance when we just do not know. We must also try to communicate effectively and make sure that we do not lose the confidence of the general public.

## MEDICAL REHABILITATION RESEARCH

Question. The field of medical rehabilitation research is thought by some people to be in need of more attention and more coordination. Disparate activities currently exist in several NIH Institutes as well as in other parts of DHHS and other Federal agencies. What fields of endeavor are encompassed within "medical rehabilitation research," and where are they currently being pursued?

Answer. NIH research in this important field is focusing on elucidation of the disease processes by which normal function is lost, developing ways to halt the progress of these processes and restore function, and developing new technologies to improve the overall quality of life for the disabled. More specific examples include: the surgical repair and replacement of lost soft tissue, bone, and teeth in cases of trauma or as a result of treatments for head and neck cancer and other disabling conditions; visual adaptation to the loss of an eye at an early age; studies related to closed control of functional neuromuscular stimulation; and determinations of the value of physical exercise in improving the quality of life of persons with cerebral palsy, osteoporosis, diabetes, or heart disease. A variety of devices and prostheses for maintaining function or improving quality of life have been developed and/or evaluated: mechanical limbs, an artificial sphincter muscle for bladder control, a robotic walking chair, and an oral prosthesis that aids in chewing and swallowing. Other examples of recent technological research that benefit the disabled are graft repair of aortic aneurysms in Marfan's syndrome patients, and development of a cochlear implant that restores meaningful speech understanding in patients with profound cochlear hearing loss. Also within the NIH, the Warren Grant Magnuson Clinical Center's Department of Rehabilitative Medicine Consultation Service provides full evaluation and treatment to all patients with functional problems in activities of daily living and mobility who are referred by NIH physicians.

Medical rehabilitation research is conducted and/or supported by 12 NIH components as shown below.

Rehabilitation-Related Research
(Dollars in thousands)

| | 1987 Actual | 1988 Estimate | 1989 Request |
|---|---|---|---|
| NCI........ | $ 2,800 | $ 3,800 | $ 2,700 |
| NHLBI...... | 1,952 | 2,025 | 2,200 |
| NIDR....... | 4,677 | 4,771 | 4,866 |
| NIDDK...... | 5,074 | 5,200 | 5,500 |
| NINCDS..... | 30,382 | 32,303 | 34,484 |
| NIGMS...... | 407 | 175 | 175 |
| NICHD...... | 20,150 | 21,300 | 21,150 |

| | 1987 Actual | 1988 Estimate | 1989 Request |
|---|---|---|---|
| NEI........ | 2,828 | 3,100 | 2,500 |
| NIA........ | 15,677 | 17,104 | 17,959 |
| NIAMS...... | 2,096 | 2,203 | 2,414 |
| DRR........ | 11,792 | 12,749 | 13,361 |
| NCNR....... | 627 | 700 | 740 |
| Total.... | 98,462 | 105,430 | 109,049 |

Question. Do you feel that greater emphasis on this research area is needed, and/or that research efforts would benefit by coordination through some centralized entity?

Answer. We believe very strongly that the rehabilitation research conducted within the NIH should remain tethered to its scientific base. Rehabilitation studies involving a certain disease or disorder should remain within the Institute that addresses the specific problem, to avoid fragmentation of the research effort and to take full advantage of scientific advances made in related areas.

Already in existence within the Department of Education is the Interagency Committee on Handicapped Research, which includes representatives of 20 agencies. The purpose of this group is to promote and coordinate rehabilitation research within the Federal Government. The Director, NINCDS, is the NIH representative to the committee.

Question. What role should NIH play in the promotion of medical rehabilitation research?

Answer. The NIH already has a significant investment in basic and clinical research that is leading to improved quality of life for the disabled. Specific authorization to conduct research related to medical rehabilitation is outlined in section 405(b)(1)(A) of the Public Health Service Act. The Directors of the national research Institutes are mandated to "encourage and support research, investigations, experiments, demonstrations, and studies in the health sciences related to...the rehabilitation of individuals with human diseases, disorders, and disabilities." In addition, the NIH will continue to participate in the Interagency Committee on Handicapped Research, which is an effective means of coordinating and fostering Federal programs of rehabilitation-related research and of sharing and promoting our plans for the continuation of a substantial involvement in rehabilitation-related research.

## FACILITIES

Question. Last year you indicated that NIH was engaged with the National Science Foundation in a comprehensive survey to clarify the nature and distribution of the need for research facilities support. What is the status of that survey?

Answer. The data collection period for the 1987-88 Survey of Scientific and Engineering R&D Facilities at Colleges and

Universities was completed at the end of March. The response rate was about 90 percent. Since that time, the data have been edited and checked for completeness, requiring a necessary follow-up with many respondents. The analysis is now beginning, and the final report will be submitted by NSF to the Congress on schedule.

Question. What recommendations can you make at this time about NIH's role in improving the Nation's research infrastructure?

Answer. At the request of the Senate Appropriations Committee, an ad hoc NIH Study Group consisting of leaders from colleges, universities, and nonprofit research institutions met to review the existing evidence on the needs for and deterioration of biomedical research facilities and equipment; the roles that the Federal Government and non-Federal sectors should play in funding those needs; the different mechanisms that could be made available to finance these needs; and to make recommendations on a pilot research facilities construction program at NIH. The report is currently being reviewed within the Department.

## SUPPLY AND DEMAND OF PHYSICIANS

Question. According to some surveys, the public is told that there is an oversupply of physicians. Lately, another survey, aired over a local radio broadcast, proclaimed that quite to the contrary, there is a shortage of physicians. What is the real situation: Do we have too many or not enough physicians?

Answer. A survey done in 1981, which simply measured the number of M.D.s per 100,000 citizens, indicated an oversupply of physicians extending well into the 1990's. That surplus, however, is principally seen in the large number of physicians in more lucrative subspecialties. There is increasing evidence that an undersupply of physicians exists in primary care disciplines.

Other studies indicate a shortage of physicians after the year 2000 due to two aspects of the baby boom population bulge. The physicians from that bulge (1946-1964) will begin retiring in large numbers after the year 2000, and the population bulge itself will reach an age requiring more medical care. These two factors could combine to produce a severe shortage of physicians in the next 20 years.

Question. What about biomedical research manpower: Do we have enough or not enough?

Answer. The Institute of Medicine reports that we are facing a period of falling enrollments in graduate and professional schools during a period of increased demand resulting from attrition, industrial needs, and the rapid expansion of science. In some areas, such as molecular biology and biotechnology, the shortage may become critical.

Question. What is your own personal assessment of the supply/demand situation vis-a-vis physicians and biomedical research manpower?

Answer. Physician-scientists are an essential component of the biomedical research manpower pool. Not only do they possess a unique perspective, translating scientific advances into improved care, but they are also the role models and faculty for medical schools necessary to train the next generation of scientists. If we are indeed facing a shortage of physicians after the year 2000, we must train sufficient numbers of physician-scientists to staff medical schools to meet future needs.

Question. How is this issue affecting enrollment in the Nation's medical training facilities?

Answer. Medical student enrollment is expected to decline by 1 percent per year for at least the next several years, due in part to the decline in the number of college entrants choosing science majors.

Question. Similarly, what is the supply/demand situation vis-a-vis dental practitioners and nursing professionals: too many or not enough?

Answer. From the late 1960s through the early 1980s, the number of new dentists graduating from dental schools rose substantially, increasing the general supply of dentists in the United States. However, trends have now reversed, resulting in a 20-percent decrease in the number of graduates each year.

On the demand side, increasing numbers of people are seeking dental care, partly because the availability of dental insurance has spread rapidly. In addition, during periods of economic growth such as those in the last 5 years, the demand for dental care also increases. Another important factor to consider is the decrease in the tooth decay rates among children and young adults in the United States over the past 15 years; retention of teeth will likely change the types of care requested, especially by the elderly. For example, more treatment will be needed for root caries, tooth wear and abrasion, periodontal disease, and various types of oral soft tissue lesions more commonly found among the elderly. In addition, dentists will have to be more skilled in treating such special patient populations as the medically compromised, the handicapped, and those with infectious diseases such as AIDS.

It is expected that the various economic, demographic, and epidemiological factors described above will interact so that supply and demand will adjust to each other over time.

With regard to the supply/demand situation in the nursing profession, the DHHS Commission on Nursing is examining this issue in detail.

Question. Are we in a situation where we now have to import professional nursing personnel?

Answer. Information presented before the Commission on Nursing indicates that such measures may be necessary.

Question. Is there a need for improved public awareness of these supply/demand issues?

Answer. It is important that the public in general and especially students choosing careers recognize that genuine needs exist for professionals in biomedical disciplines.

## FEDERAL/PRIVATE SECTOR SALARY GAPS

Question. You recently stated before the House Appropriations Committee that there was a widening salary gap between senior Federal and private sector research scientists and that the situation could seriously compromise the quality of future NIH intramural research programs. What solutions are being explored to redress this serious problem?

Answer. As you know, the National Academy of Sciences, Institute of Medicine (NAS/IOM) has been awarded a contract to examine strategies for strengthening the NIH intramural research program. The Study Committee will be addressing this issue, among others, in the course of this study.

Question. Is a study by the Institute of Medicine of this problem underway and will it be completed on schedule?

Answer. As mentioned above, the NIH has awarded a contract to the NAS/IOM to examine the barriers to, and strategies for, strengthening the scientific excellence of the intramural research program at NIH. The issue of the widening salary gap is a major topic to be addressed by the NAS/IOM Study Committee. The IOM study is scheduled to be completed by October 31, 1988.

Question. What are your thoughts about this problem and what solutions do you see emerging?

Answer. The pay gap between senior scientists in the NIH intramural program and their counterparts in academic and industry has widened significantly. In the academic sector, on the average, the compensation of senior physicians is 62 percent higher than that received by NIH senior physicians, while the base pay of senior Ph.D. academic staff is 23 percent higher than that received by NIH senior Ph.D. staff. This growing disparity has caused increasing losses of outstanding scientific talent from the intramural program and major difficulties in recruiting replacement and new talent.

Question. When the IOM study is completed, how quickly can recommended fixes be implemented?

Answer. The OMB has requested that the IOM Study Committee examine at least five strategies as approaches to maintaining the scientific excellence of the NIH intramural program. These include (1) privatizing the intramural research program; (2) establishing the intramural laboratories as a free-standing Government (within or outside DHHS) research institute; (3) changing the status quo incrementally; (4) continuing the status quo; and (5) making other organization changes.

Given the range of options the IOM study will assess and the range of recommendations that may emerge, it is not possible to determine now how quickly the recommendations can be implemented. Once the study report is received, all recommendations will be assessed in a timely fashion and proposals developed to respond to the issues.

AIDS

Question. Are there projects in which NLM could be involved that would increase access of health professionals around the country to information they need to cope with AIDS in their communities?

Answer. NLM is using existing resources to extend our current coverage to build an online AIDS Information Service that will cover the major part of the world's published literature on AIDS research, epidemiology and treatment. Depending on the availability of resources, NLM plans to (1) extend coverage of this service to research-in-progress information that has not yet reached the journal literature, by tracking available information in research grants, project reports, conference proceedings and pharmaceutical patents; and (2) build computer linkages for users to other AIDS information files located in other online systems. Access to this service will be available to the entire NLM user population of health professionals and biomedical researchers.

The Library's GRATEFUL MED software package which allows users without search training to use their personal computers to search NLM's databases successfully, is already used by many health professionals to access the citations to AIDS literature in MEDLINE and other NLM files. GRATEFUL MED, which undergoes continual testing and modification to improve its utility, will provide a very inexpensive and simple method of access to any new AIDS database mounted by NLM.

Question. What role does or could NLM play in the national effort to disseminate health education/risk reduction/prevention information on AIDS?

Answer. NLM provides information services primarily to health professionals and biomedical researchers. The CDC AIDS Clearinghouse and its AIDS Hotline will bring health education/risk reduction/prevention information to the public at large. However, it is planned to link the proposed new NLM AIDS Information Service to the Clearinghouse where this is relevant. For example, NLM plans to carry in a directory component of the NLM service listings, developed by the Clearinghouse, of organizations that provide services or materials related to AIDS.

Question. In December 1987 NLM ceased free distribution of its recurring bibliography on AIDS, which had been produced since 1983 as part of the Literature Search series. A separate quarterly publication titled AIDS Bibliography is available for $12 per year. Will this publication reach as many as the Literature Search series did?

Answer. Our new method of distribution will ensure a much wider dissemination of the AIDS literature than permitted through the former series. Our primary method of distribution had been through a mailing list of approximately 700. Because of the effort involved in the distribution, only institutions, not individuals, were eligible to be placed on this mailing list. By now making the AIDS Bibliography available through the Government Printing Office at minimal cost, we are able to take advantage of that Office's advertising and distribution methods. GPO has ordered an initial print run of 5,000 copies for the first issue, and with minimal advertising to-date the subscription list is already at 900. Once it is in print, GPO will advertise the AIDS Bibliography by issuing press releases, by including it in its new publications sales catalog which is mailed to over 225,000 subscribers, by including it in both GPO's printed Monthly Catalog and its online version (available through BRS and DIALOG), by mailing it to the nation's government depository libraries, and by advertising it at international book fairs and to foreign book dealers. We also plan to increase the utility of our publication by making it a monthly beginning in 1989.

## OUTREACH

Question. Last year the Committee directed NLM to report on its efforts to "develop an outreach program aimed at science and technology transfer of the latest scientific findings to all health professionals including psychologists, nurse midwives, and nurse practitioners in rural communities and other areas." Please summarize your efforts to reach these health professionals with your information services.

Answer. To reach these health professionals NLM is undertaking a number of activities which include the following:

- First, we aim to increase the awareness of health professionals of the helpful information services that are available to them. We plan an active program of publications, lectures, exhibits, demonstrations, and tutorials at scientific meetings.

- Second, we will step up our training of health professionals to use their own computers to search NLM's many databases. We plan for assistance in this project from Regional Medical Libraries, Resources Libraries, contract assistance, and from automated instructional programs that can be run by health professionals in their own homes and offices.

- Third, we have taken steps to eliminate a number of barriers to NLM's online systems by reducing the cost of access by students, by encouraging the use of GRATEFUL MED (both lowering costs and improving access), by extending the systems that electronically route requests for documents, and by keeping in close touch with users through surveys and scientifically designed field evaluation studies.

- Fourth, we have directed special attention to support NIH's efforts to increase availability of scientific information about AIDS.

PRESERVATION

Question. One of NLM's responsibilities is to preserve the biomedical literature so that it will be available for use by current and future generations. What response have you had to your campaign to promote the use of more permanent paper in the biomedical literature?

Answer. The two major related objectives of the campaign to promote the use of more permanent paper for the biomedical literature are to increase awareness of the need to use permanent paper among the creators and users of biomedical literature and to translate that awareness into action.

Response to the effort to increase the awareness has been reflected in news items and articles about the problem of paper deterioration and the Library's campaign for its resolution in the following periodicals: American Association of Publishers (AAP) Professional and Scholarly Bulletin, AAP Monthly Report, American Medical Publishers' Association Newsletter, Authors Build Bulletin, Council of Biology Editors Views, Documents to the People, The Economist, Journal of the American Medical Association, Library Journal, Publishers Weekly, Scholarly Publishing, and Science. Another half dozen preservation and library publications carried the Library's message to their professional readers. It was also noted in the Congressional Record.

Representatives of 16 publishers responsible for some 400, or one fifth of the North American and European journal titles in the Index Medicus have agreed to participate in the Library's 34-member Permanent Paper Task Force. They will explore ways to increase the proportion of their own titles now on permanent paper and to enlist more of their peers in fostering market conditions favorable to increase permanent paper utilization.

Question. What do publishers and paper manufacturers tell you about the economics of more permanent materials?

Answer. Paper manufacturers agree that the cost of making paper using the alkaline process, i.e., the process that results in permanent paper, is lower than that of using the acid sizing process. It permits substitution of less expensive for more expensive materials, reduces water consumption and energy requirements, facilitates waste treatment and compliance with environmental controls, and is cleaner and on balance, less corrosive to machinery. The process of conversion to the alkaline process is acknowledged to be predominantly cost motivated rather than end use directed. Alkaline papermaking capacity is in use for making a variety of kinds of paper; only one half of it is currently devoted to printing and writing, sheet paper needs.

The observation of publishers who are current users of permanent paper is that it is available in commercial quantities and at competitive prices for comparable grades. It has been confirmed by a price comparison survey by the NLM Permanent Paper Task Force. A proof of it is that some publishers are using permanent paper and don't know it; similarly, there are manufacturers who are marketing permanent paper on its features other than permanence. The concern of some publishers that a cost increase might follow conversion to permanent paper use appears to be based on their earlier experiences. A major upsurge toward alkaline papermaking has taken place only during the last five years.

## ONSITE USER OF NLM COLLECTIONS

Question. In your justification document (p. 235), you describe a problem with commercial information brokers making very heavy use of materials from the Library's closed stacks, thereby increasing the number of requests your staff must handle. You indicated that you were implementing a six month test, reducing the number of requests you will provide to each patron from 60 to 10 a day, with provision for an overnight photocopy service for high volume patrons. How is this test working out?

Answer. The test is in its third month. During the first two months, March and April, the number of stack requests accepted from onsite patrons dropped, on average, 43%. The March-April total in 1987 was 61,089; in 1988 the two-month total was 34,942. The percentage filled was 83%. Historically, the fill rate for stack service ranges from 81% to 87% in any particular month, and we did not expect the fill rate to increase during the test. The most significant improvement in service has been in reduced delivery times. In January of 1988 only 59% of the filled requests were delivered to patrons within 30 minutes. In February the figure dropped to 42% in 30 minutes. In March and April, on average, 65% of the filled requests were delivered within 30 minutes.

The Overnight Photocopy Service started at the same time the number of stack requests was reduced to ten per day. During March and April the daily average of requests submitted was 35. All the requests submitted were processed overnight and made available for pick-up the next morning. Those using the service have been generally satisfied though we had expected a higher volume.

Question. Have non-commercial patrons (individual scholars, researchers, students, other health professionals) been inconvenienced by this policy?

Answer. The decision to reduce the number of stack requests to ten was based on data that clearly showed that 95% of the Reading Room patrons, on average, requested ten or fewer items per day from the stacks. While there has been some negative feedback from individual health professionals most of those who have voiced an opinion have been very positive about the new system. The most common comments have focused on the improved delivery times and the overall atmosphere of better organization and control in the Reading Room. The few health professionals who have had document needs exceeding ten per day have been handled on an exception basis. In every case we have provided the higher number requested.

FTE's

Question. In your intramural program you are proposing to operate with six fewer FTE's than you have in FY 88. In what activities will you feel the loss of these people?

Answer. The proposed staffing reduction will be distributed as follows: Library Operations will be reduced by four FTE's and the Lister Hill National Center for Biomedical Communications and the Toxicology Information Program will each be reduced by one FTE. These reductions are possible through our Management Improvement Program.

Question. What is the "Management Improvement Initiative" identified in the justification document as responsible for this decrease in FTE's?

Answer. The Management Improvement Initiative is our part of the President's overall program calling for management review and improvements to streamline, simplify, or improve the delivery of Federal government services or the use of resources.

NATIONAL CENTER FOR BIOTECHNOLOGY INFORMATION

Question. The new National Center for Biotechnology Information was established in FY 88 within the Lister Hill National Center for Biomedical Communications, NLM's intramural research organization. Its focus will be the provision of enhanced biotechnology information services to assist researchers in analyzing, recording, and retrieving genetic molecular data more efficiently and effectively. What are the major problems to be overcome in coordinating new and existing databases in biotechnology?

Answer. Biotechnology encompasses both the basic research of molecular biology which seeks to understand complex life processes at a fundamental chemical level, and the use of molecular tools to change the genetic blueprint of living species, resulting in unprecedented opportunities in medical diagnosis and therapy, agriculture, and industry. More than any other area of biology and medicine, Biotechnology has acquired an absolute dependence upon computers to acquire, store, analyze, and communicate data. This has occurred because living cells are made up of billions of molecules, and many of the largest of these molecules (called "macromolecules") are made up of millions of atoms. Each of the ten trillion cells in our body contains a genome made of three billion units of DNA. Much of scientific progress relies on the discovery of key molecular patterns among oceans of cryptic symbols representing atoms and molecules, and computers offer the only feasible method of finding and analyzing these patterns. The challenges to database builders in this rapidly changing area of science include the following six problems:

1. Accommodating the explosive growth of molecular genetic data--A major challenge is simply keeping up with the pace of scientific discovery. New automated methods allow laboratories to analyze complicated molecules and to create new molecules hundreds of times faster than was possible only five years ago. As a result, for example, the GenBank DNA database is growing at the rate of over 1 million computer characters (bytes) per month, and is doubling in size every 13 months. Currently, GenBank contains less than one tenth of one percent of the human genome.

   Close coordination between databanks and the over 100 scientific journals which publish biotechnology research papers is desperately needed to reduce current backlogs of data and increase the capacity of databanks and journals to process new research findings. New computerized tools which allow researchers to submit their data to central databanks in "machine readable" format are under development, sponsored in part by the NLM. As well, the NLM is assisting in the more efficient building of DNA database records by providing literature surveillance for new articles describing DNA sequences, and providing computerized records of these articles to the GenBank database builders at the DOE labs at Los Alamos.

2. Accommodating advances in scientific understanding--The way that data is represented in computer files reflects the current understanding of life processes. As our collective view of molecular biology changes with the discovery of new mechanisms in cells, tissues, and intact organisms, it sometimes becomes necessary to rewrite the way that data are described and analyzed. An example is the remarkable and frightening speed with which the AIDS virus mutates to form genetic variants. No longer can a single, static computer record contain the "AIDS virus genome"; instead, computer programs must depict a variety of possible molecular sequences and structures, with notations as to the date and location that new molecular changes occurred in previously analyzed virus samples. As our understanding of biology grows and changes, so will the major databases need to change. Each time a major database changes its format or structure, there is a ripple effect which requires coordination with other related databases and value-added resellers which may require new computer programming and data processing steps.

3. Accommodating advances in computer hardware and software--Many of the key molecular biology databases have been constructed using editing tools not much different than word processors. Although these data formats sufficed when the databases were small and amenable to scanning by the unaided eye, as the databases grow into millions or billions of entries, more highly specialized organizations of the data are needed. An example is the change currently underway to convert the original GenBank record format (built with simple text editor programs) to a "relational database format" which allows rapid data searching, analysis, and updating. New and specialized computer architectures such

as "massively parallel processors" can increase the speed of molecular comparisons by 1000 or more times over conventional computers, but these computers require complicated reformatting of molecular data. Each time a new technical advance appears in the field of computer science, and is adopted by one or more molecular biology databases, there is a new coordination effort to be undertaken, to educate and inform builders of other biology databases as to how they may link the new data formats to their own.

4. Development of standards for sharing of data--Because there are so many different types of computers in use in biology, and because many different arrangements of the same data are needed for various types of analysis, it is unreasonable to expect that all researchers will ever use a "uniform format." What can be done, however, is to get a consensus among database builders and researchers on standards for data sharing. This is, in essence, getting agreement on the ways by which information is "packaged" for shipment to other computer systems. Currently, no such standards exist, and only the first efforts are underway to develop such standards for DNA databanks. Substantial work remains to create and obtain agreement on data exchange standards for biotechnology databases which contain data from proteins, crystal structure, chromosome maps, and other types of molecules such as carbohydrates. The NLM is currently participating in the development of standards for sharing of DNA data, but a major national focal point for the larger work of general biological information standards still needs to be created.

5. Adoption of uniform nomenclatures and controlled vocabularies--The key to the successful understanding of new discoveries is the consistent use of new and existing terminology to describe them. Currently, there is no standardization among the major biotechnology databanks about names of organisms, species, cellular components, or special purpose molecules. Although names are often similar, even minor disparities often prevent computer searches and analysis from succeeding from one databank to another. Researchers speak many hundreds of different dialects of the language called Biology, and the lack of common terminology impedes the sharing and understanding of similar data, and impedes progress in the field. The NLM is currently working with two major NIH-supported national databanks of DNA and proteins to develop common searching vocabularies and terminology.

6. Providing easy access to multiple databases--The major national and international databases of Biotechnology are highly specialized: each stores the data of a particular class of molecules. Thus, there are DNA databanks, protein databanks, genetic map databanks, and protein crystal structure databanks. But though these data sources are independent and disconnected, the information they contain is very closely linked in the mind of the scientist. Developing computer systems which allow biologists to simultaneously view and easily retrieve data simultaneously from multiple related databases, perhaps located at many different sites around the world, is a major challenge. The

NLM is developing prototype systems which address this key issue of integration of data and easy, simultaneous access.

Overall, the problems of coordination of new and existing databases stem from the fact that these databases exist at the junction of two rapidly changing fields of research and development: molecular biology and computer science. Whenever a technical field is in flux, there is a special need for communication, education, and coordination among the institutions and individuals working at the frontiers of new knowledge. In the information handling of Biotechnology, there are two highly complex technical fields changing rapidly, and the best of both will be realized only if a concerted effort at coordination is undertaken.

Question. Is the pool of researchers and trained personnel in the biotechnology information field adequate to address these problems?

Answer. Given the time that is required to become proficient as a molecular biology researcher, and the time required to master the principles of modern computer science, it is not surprising that there are a very small number of scientists who work at the union of the two disciplines, probably less than 50 nationwide.

In addition to a relatively small cadre of researchers and specialists working at the interface between biology and computer science, it is clear that efforts will need to be devoted to instructing every interested biological researcher in the use of the computer as an instrument for managing research information. Skills such as database searching, use of key analytical programs for molecular sequence and structure, and using computers for communications of data between laboratories need to be taught widely throughout the biological community, which lags behind the physical science communities in its adoption of new information technologies.

The NLM has sponsored a number of workshops in its own computer training facilities to instruct researchers in the use of computers for molecular analysis, and has sponsored a recent scientific conference on new methods of computer analysis of DNA and proteins, but there is a need for much broader scale support for training in this field.

## MEDICAL INFORMATICS

Question. Medical Informatics has been identified as a high priority initiative in NLM's Long Range Plan. This new discipline addresses ways in which computers and information technology can be used to organize and manage constantly increasing biomedical information and knowledge. Are your training resources in this field sufficient to keep up the supply of personnel for openings in medical informatics at the nation's academic medical centers?

Answer. NLM's training programs have been successful in recruiting able and talented young scientists and physicians who are attractive candidates for faculty track positions in the nation's academic medical centers. There is growing recognition that management of knowledge, particularly in a computer context, is a necessary part of medical education. While its place in the curriculum may not be extensive, it influences clinical behaviors throughout one's early professional formation, is likely to play a major role in future medical practice and continuing education, and is a critical skill for the conduct of biomedical research. To a somewhat lesser degree the same is true of other health professions. The need is to find qualified persons who can teach medical informatics in academically relevant ways. In addition to teaching competence, academic medical centers seek persons who can organize medical informatics divisions or departments, collaborate in the management of major information resources, and contribute to research in this field.

In addition to those who combine clinical competence with medical informatics training, there is a growing need for Ph.D.s who can address research issues in the basic sciences. A particularly acute example is knowledge retrieval in molecular biology, where solutions of information problems are critical to new advances in molecular genetics. The growing acceptance of concepts for integrated academic management information systems also gives rise to a need for persons with informatics and executive skills to manage and direct vast and costly arrays of medical information resources.

Question. Are sufficient resources available to support research grants in this discipline? (In the Justification, p. 235, it is noted that "Funds are available to support existing research grants and other significant projects have been approved for award should resources be forthcoming.")

Answer. The 1989 request will fund 20 grants. We believe this is an acceptable level of support. As is the case with all NIH grant programs, a backlog of approved applications is available if additional funds are available from within NLM.

## EXTRAMURAL RESEARCH SUPPORT

The number of extramural grants supported by NLM has dropped by 32 percent over the last two years, from 90 in FY 87 to 74 in FY 88 to a projected 61 in FY 89. The funding for these grants, however, has increased steadily from $11.9 million in FY 87 to $12.2 million in FY 88 to $12.7 million in FY 89. Most of the decrease in the number of grants has been in the competing projects category, while most of the increase in the funding has been in the noncompeting continuations category. This has resulted in a wide discrepancy in the average cost of grants, as shown in the table below.

AVERAGE COSTS OF NLM EXTRAMURAL GRANTS

|  | Noncompeting Continuations | Competing |
|---|---|---|
| FY 87 Actual | $6,826,000/46 grants - $148,000 aver. cost | $5,077,000/44 grants - $115,000 aver. cost |
| FY 88 Estimate | $8,206,000/47 grants - $175,000 aver. cost | $3,983,000/27 grants - $147,000 aver. cost |
| FY 89 Request | $10,337,000/42 grants - $246,000 aver. cost | $2,340,000/19 grants - $123,000 aver. cost |

Question. What accounts for the large increase in the average cost of continuation grants?

Answer. There are a number of factors in addition to normal inflation that contribute to the 66% increase in the average cost of continuation awards from 1987 to 1989. For example:

- o Incorporated in the averages are data from the Medical Informatics program area. Continuation award averages for this activity during the same three fiscal years are $215,000; $230,000; and $345,000. However, if these average figures are adjusted by eliminating a single, unusually large award ($1 million/year for five years beginning in 1985), the resulting averages are: $149,000 (87), $133,000 (88), and $267,000 (89). Such adjustment would similarly impact on the overall NLM averages.

- o Budget data available to the Congress for 1988 and 1989 include estimates for the newly initiated Biotechnology program--an area without NLM history concerning average costs. One million dollars was estimated in early 1987 to be adequate to fund four biotechnology awards at $250,000 per award. As of April 23-24, 1988 when the application review took place, it can now be confirmed that funding will be possible for 7-8 biotechnology grants. Consequently, the average competing award in 1988 would be reduced from $147,000 to $128,000 and the continuation awards in 1989 would be reduced from $246,000 to $225,000.

- o In 1987 NLM's training program was recompeted to increase the number of awards and expand the number of trainees. In that year, seven awards were newly competed and averaged $268,000 per year. Only one was awarded a continuation grant at $200,000. In 1988 no new competing awards were made; however, eight awards at an average cost of $336,000 are included in the continuation award data. Therefore, averages, new and competing during 1987 and 1988, are very significantly influenced by the training activity described.

Question. What areas of research grant support are you not able to pursue because of the 57 percent drop in the number of competing projects since FY 87?

Answer. As you state in your previous question, funding for NLM grants has been increasing. Therefore, research areas have been affected only by shifts in program emphasis.

Question. The average costs of competing grants under the request will be a 16 percent decrease compared to FY 88 costs. What will be the effects on your grantees of this decrease in the average size of available grants?

Answer. Most of our applicants say they will reduce staffing levels and proceed with the research more slowly. In some cases, projects cannot be scaled back, and alternative research strategies must be sought. Nonetheless, total grant funding would increase 4% over FY 88.

Question. Have you increased the amount of cost-sharing required of institutions receiving medical library resource grants?

Answer. No. The matching requirement of $1 dollar Institutional to $4 Federal has been in effect for Resource Improvement Grants for approximately 10 years. There are no immediate plans for modifying this requirement.

"Sharing" under other Resource Grants (Projects) is governed only by the grantee's assurance of "adequate continuing financial support--from other sources during and after the (grant) period." There is no dollar matching stipulation associated with these awards. This legislative language has remained unchanged since the original 1965 Law and is considered one of the strengths of the Resource Program. Conservatively estimated, the assurance has increased the institutional impact of these awards by tenfold.

## EPIDEMIC DISEASES AND INTERNATIONAL COORDINATION

Question. Since 1968 you have endeavored to bring together an international community dealing with major epidemic diseases, including most recently, AIDS. What progress has been made with the problem of the AIDS epidemic through your activities over the past year?

Answer. The dissemination, nationally and internationally, of information on advances in AIDS research and treatment is critical. The FIC made a number of efforts to accelerate this process. For example, the FIC was lead organizer for the III International Conference on AIDS, held in Washington, D.C., which provided the opportunity for over 7,000 scientists, public health officials and media representatives to exchange information and to discuss recent research findings. The conference resulted in numerous scientific publications and articles on AIDS, including the "FIC Summary Report on the III International Conference on AIDS". This year, the FIC has committed support for investigators presenting papers at the IV International Conference on AIDS, in Stockholm, Sweden. The FIC participated in and partially supported the Second International

Conference on Antiviral Research and the Pan American Conference on AIDS in Guadalajara.

The FIC's main AIDS efforts are associated with two new award programs: the Special International Postdoctoral Research Program in AIDS, and the International Training Grants in Epidemiology Related to AIDS.

Question. Is your budget sufficient to bring together the human resources necessary to deal with all of the major contagious diseases?

Answer. The federal effort dealing with control and eradication of major contagious diseases is a combined effort involving resources and scientists from a number of federal agencies including the National Institutes of Health, the Centers for Disease Control and the Food and Drug Administration. The FIC has and continues to be involved in studies and conferences dealing with approaches to improve international control of major contagious diseases, including polio, measles, congenital rubella, and yaws and other endemic treponematoses. Current studies are primarily focused on tuberculosis and hepatocellular carcinoma. Though we cannot realistically study every contagious disease, our resources are adequate to periodically address those diseases of major international importance which are amenable to control through identification of research needs and development of strategies for worldwide control based on state of the art technologies.

Question. Have you made progress in soliciting support from other countries, particularly countries south of the equator?

Answer. The FIC has been particularly gratified by the interest expressed by Latin American countries (Brazil, Dominican Republic, Mexico, Ecuador, Costa Rica, Guatemala, Jamaica, Haiti, Peru, Colombia, Venezuela, Chile and Panama) in our major new programs dealing with AIDS.

In addition to direct country involvement, the Pan American Health Organization has expressed a strong interest in our new training initiative which is designed to increase the self reliance and capability of scientists in other countries in the Region to conduct their own epidemiologic research related to AIDS and to utilize epidemiology in clinical trials and prevention research. In this regard international collaboration is considered essential in the world's battle against AIDS.

Question. What in your view can the FIC do to better coordinate international efforts directed toward eradication of tropical diseases and AIDS, and how can this committee help toward that end?

Answer. Although research directed toward the control of tropical diseases and AIDS is largely the responsibility of other components of the NIH, the FIC's efforts related to AIDS primarily involve two major new programs: the Special International Postdoctoral Research Program in AIDS and the International Training Grants in Epidemiology Related to AIDS. The major emphasis on training in these programs is designed to strengthen the capability of other countries to conduct their own AIDS research. These requests for applications (RFAs) have elicited a substantial response from the academic community. Our program on international training grants in epidemiology related to AIDS was structured to be responsive to the guidance contained in the Senate appropriations language for FY 1988 and helps to meet a major need in the world's battle against AIDS.

The strategy to strengthen the infrastructure for international research related to AIDS can ultimately be extended to support efforts in tropical disease research as well. The FIC hopes to help build the research manpower base for a long-term sustained commitment to international health research in collaboration with other institutes, particularly NIAID and NCI.

Apart from responding to training needs related to AIDS, the FIC has worked closely with staff from the WHO Special Program on AIDS to help respond to emerging needs in this area.

## FOREIGN SCIENTISTS TO THE U.S.

Question. It is stated in your advisory board biennial report to Congress-FY85 and FY86- that: "There is at present no mechanism in the area of individual awards in biomedical research or advanced training, for senior foreign scientists to come to U.S. institutions for collaborative research activities." You suggest that a solution to this might be research fellowship awards. Doesn't the FIC already have in place a system of research fellowship awards through advanced studies programs, international coordination and liason program, and foreign scientist program?

Answer. The FIC does have a fellowship program for foreign scientists, but it is limited to relatively junior scientists--those with less than ten years of postdoctoral research experience.

The Advanced Studies Programs consist of: the International Studies Program which supports studies on international aspects of biomedical and behavioral research, research manpower training, and the transfer of research results to health care systems; and the Scholars-in-Residence Program which makes a limited number (approximately 10 per year) of awards to prestigious (Nobel laureate level) scientists to come to the NIH to work on advanced basic science topics with senior scientists exclusively at the NIH.

The International Coordination and Liaison Program supports short-term biomedical research or health scientist exchanges with a limited number of countries (i.e., Austria, Bulgaria, France, Hungary, Poland, Romania, the Soviet Union and Yugoslavia). The purpose of these exchanges, which range from 2 to 12 weeks, is to support short-term collaborative studies or to explore prospects for longer-term collaboration.

Under the Foreign Scientists Assistance Program, the FIC provides visa and administrative assistance to foreign scientists who come to NIH intramural laboratories under the NIH Visiting and Guest Researcher programs.

Question. Couldn't those programs be modified to accommodate the perceived needs of your advisory board?

Answer. The International Research Fellowship Program, which currently focuses on providing research training in the United States for junior foreign scientists, could be modified to accommodate senior foreign scientists as well.

Question. How large would stipends for senior foreign scientists have to be on the average?

Answer. The cost for each participant would range from $52,000 to $70,000, including stipend, living allowance, travel costs and host institutional allowance to cover research costs.

## Host Responsibilities

Question. It was stated in the above-mentioned Advisory Board Report to Congress that, "very limited funds for host reponsibilities are provided through standard appropriation channels, and none at all are provided in the appropriation to FIC." Please explain: Has this committee overlooked that problem?

Answer. We are not requesting additional appropriations to defray our host responsibilities. It would be helpful, however, to have increased authority to use our appropriated funds for this purpose.

Question. Can you estimate what additional monies would be needed for this function?

Answer. No additional monies are needed. However, an increase in representational authority would allow for meeting the demands of current host responsibilities.

## ALTERNATIVES TO THE USE OF RESEARCH ANIMALS

Question. The Division of Research Resources supposedly assisted NIH three years ago to produce a plan for research methods that do not use animals. DRR is to have reissued a new plan for a NIH wide program in February, 1988. At present are there any commonly used alternative validated research methods that have replaced whole animal models in biomedical research?

Answer. Yes. Classic examples exist. Included among these is the current enzyme assay for pregnancy in humans, a test that originally used rabbits, later frogs and now uses no animals at all. An assay, originally involving live chickens, which now is done in vitro, tests a substance's potential as a neurotoxic agent. Tissues in culture have been and continue to be employed as fundamental, valid models for studies in some major areas of biomedical research.

Production of viruses and antibodies using cells in culture is another example of valid, non-animal methods which have replaced the use of live animals in some areas of research.

Question. Are members of animal rights groups accurate in their assertions that such alternatives have existed for quite some time and that biomedical researchers have refused to adopt such alternatives because of their traditional reliance on whole animals?

Answer. There have been many examples of what the animal rights groups call "alternatives" that have been developed for use in biomedical research. The studies with peas and fruit flies provided the foundations of our knowledge of genetics. Studies on yeast provided the basis for our understanding of how all cells, including human, convert food to energy and then construct the fundamental cellular components essential to life. Our knowledge of the processes of fertilization, the initial events taking place when sperm and egg combine, stems from studies on sea urchins.

Live animals are used in research when they are the model system of choice for the specific research question posed, but whenever alternative methods can be effectively used they generally are employed. NIH sponsored an in-depth analysis of the use of nonmammalian organisms in biomedical research through the National Academy of Sciences. The report from the study, "Models for Biomedical Research; A New Perspective", shows how "alternative" systems have been and are used in biomedical research, and has stimulated a detailed exploration of how scientists can better utilize the knowledge contained in the voluminous published literature.

## CHIMPANZEE MANAGEMENT PLAN

Question. During the summer of 1987, the Congress was deluged with letters expressing concern with a program called the Chimpanzee Management Plan. The plan is a chimpanzee breeding program which supports five research grants or contracts that total $2,500,000. One goal of the plan was to produce 60 infant chimps per year, some of which would be used for research while others would be used for further breeding. Many, if not all of the letters, called for an outright ban on the spending of taxpayers dollars for this breeding program. Will the funding for the chimp breeding plan continue and if so, for how long?

Answer. Funding for the Chimpanzee Breeding and Research Program began in FY 1986 with an initial project period of four years. The last year of the initial project period is FY 1989. Careful review will be required in 1990 to determine how, and if, the program should be continued. Since the generation time for the chimpanzee is approximately 11 years, preserving the chimpanzee species is a very long term effort. The future demands on the supply of chimpanzees must be carefully projected and planned for, so that we do not inadvertently deplete our scarce chimpanzee resources. Based on experience with the development of the Hepatitis vaccine, which also involved the use of chimpanzees, we are estimating that many more animals will be needed than can be drawn from current supplies.

Question. Would termination of the plan cause havoc in the availability of chimps for research purposes? (Many of the letters received asked for members of congress to terminate the plan.)

Answer. Yes. Just over 100 chimpanzees have been used in AIDS research to date. About 300 chimpanzees previously used in hepatitis B research studies are available for AIDS research. Only a very small number of animals not previously used in the hepatitis studies have been used in AIDS studies. Use of these naive animals will be kept at the lowest possible number through protocol review by the NIH AIDS Animal Models committee which reviews all Federally-funded AIDS protocols requiring chimpanzees. Based on experience gained in developing the hepatitis vaccine, we know that many more animals will be needed. The Chimpanzee Breeding and Research Program will eventually produce about 60 animals per year. Some of them will be for preservation of the species, and some will be for research. At this rate, research projects using the chimpanzee as a model in AIDS research, biotechnology testing, or neurobiology research will be very limited over the next few years. Since the chimpanzee so closely resembles the human organism in so many ways, it is an excellent animal model for the study of human diseases. An insufficient supply of chimpanzees, which would result if the plan were terminated, would produce significant delays as well as many missed research opportunities for biomedical research scientists.

Question. Has the plan been successful, or in other words, have the primate breeding centers involved in this project been able (collectively) to produce the intended goal of 60 chimps per year?

Answer. The first awards in the Chimpanzee Breeding and Research Plan were made in September, 1986. In the beginning, renovations had to be made to facilities, staffs had to be hired, chimpanzees had to be assigned to groups, and policies and procedures had to be developed before full production capacity could be attained. In spite of these startup delays, the 1987 production figures show an increase of 27 live youngsters. The generation time of the chimpanzee is about 11 years, and their gestation period is nine months. Last summer, two sets of twins were born, the first chimpanzee twins to survive in the United States. Once the program is fully underway we expect to achieve production of approximately 60 chimpanzees per year. This is the only funded and productive chimpanzee breeding program in the United States, and provides the best hope for preserving the captive chimpanzee supply in the United States.

## GENOME MAPPING IN THE BIOMEDICAL RESEARCH SUPPORT PROGRAM

Question. The Biomedical Research Support Program within DRR is designed to promote innovation in the biomedical sciences. Some BRSG grant funds have been used to support projects related to mapping the human genome. In the arena of "big science" the human genome mapping project is predicted to be quite costly with estimates running somewhere between several hundred million to a couple of billion dollars.

How much money is the Biomedical Research Support (BRS) Program contributing to the genome mapping project?

Answer. The most current annual data indicates that 132 genome mapping and DNA sequencing projects were supported with $874,865 in BRS grant support. Of the total, 27 projects were for human genome mapping at a cost of $203,451.

The Shared Instrumentation Grant Program of the BRS Program provided a total of $689,756 for genome mapping projects including $131,904 for support of projects related to mapping of the human genome.

Question. What specific aspect(s) of the genome project is its money supporting?

Answer. Specific human genome mapping projects include studies of the Wilson's disease gene, identification of the cystic fibrosis gene locus, mapping of the hemochromatosis locus and studies of the molecular regulation of human transplantation genes.

Question. Is this a one-time cost or will there be a yearly need for this kind of expenditure as research on AIDS continues?

Answer. The BRSG is often used to support new investigators and established investigators who would like to change their area of research interest. As new initiatives unfold, such as AIDS research and the human genome mapping project, it is important to have a mechanism in place to encourage research workers to meet changing priorities in national objectives.

## 1989 BUDGET REQUEST

Question. The 1989 budget request for the Division of Research Resources is $319,977,000, a modest increase of 0.7 percent over the 1988 level. Are certain programs or activities going to be eliminated under this budget?

Answer. No programs or activities will be eliminated under the 1989 budget request.

Question. If additional funding were made available in 1989 which activities would have the highest priority for increased spending?

Answer. If additional funding was available in 1989 our first priority would be to restore full direct cost funding to the ongoing general clinical research centers, biomedical research technology centers, primate research centers, laboratory animal sciences centers, and minority biomedical research support grants. Second,
we would provide additional funds to expand the biomedical research support grant program. Third, we would propose to add approximately five new GCRCs, six new BRT centers, six new LAS centers, and four new MBRS awards. At this time, these are our highest priorities.

Question. Provide examples of high versus low ranking priorities.

Answer. Our high priorities are, of course, to maintain ongoing general clinical research centers, biomedical research technology centers, primate research centers, laboratory animal sciences centers, and minority biomedical research support grants at their full direct cost level.

During the preliminary budget cycle, as we developed our 1989 President's Budget request, we were asked to rank our priorities and make sound programmatic judgments as to which activities should be expanded and which should be eliminated based on the relative scientific merit of each project. As a result, any low ranking priorities were eliminated very early on in the preliminary budget process.

## RESEARCH CENTERS IN MINORITY INSTITUTIONS

Question. Dr. Pickett, can you please tell us how the program of Research Centers in Minority Institutions is progressing?

Answer. The Research Centers in Minority Institutions (RCMI) Program which made the first eight awards on September 30, 1985, and seven additional new awards in fiscal year 1986, is progressing well. Some examples of the impact of the program are:

- at Meharry Medical College in Nashville, Tennessee, the addition of five scientists has expanded the department of physiology so that a Ph.D. program in neurosciences can be offered. The proposed program has been reviewed by an external body and awaits final approval. It is anticipated that the first four graduate students in the new program will be admitted this fall. This should lead to a substantial expansion in the number of well trained minority neuroscientists who can address important research questions such as more effective management of post-stroke victims, the underlying causes for the disproportionate incidence of essential hypertension in blacks and other minorities, and factors which govern the action of the AIDS virus on the central nervous system;

- at the Morehouse School of Medicine in Atlanta, Georgia, technical support for junior faculty will assist young scientists to do preliminary studies that will help them compete for independent research support. A number of faculty successes are already evident, with competitive grant support from the National Heart, Lung, and Blood Institute; the National Institute of Diabetes and Digestive and Kidney Diseases; the National Eye Institute; the National Science Foundation; and the Division of Research Resources;

- a nationally based computer network has been established among 6 grantee institutions which enables faculty to do simulated gene cloning and sequencing, aided by the donation of software for molecular biology by Battelle's Pacific Northwest Laboratories and the Digital Equipment Corporation;

- plans are underway to assist RCMI institutions to develop the necessary research infrastructure for participation in AIDS research and AIDS-related research. This is a critical need since 40% of the AIDS cases reported to date are in Blacks and Hispanics.

Question. How many schools are participating in this important program?

Answer. Fifteen institutions are currently participating in the RCMI Program. The recipients include two colleges of pharmacy, seven medical schools and six graduate schools, located in Hawaii, California, Texas, Tennessee, Georgia, New York and Florida, as well as in Washington, D.C. and Puerto Rico. A sixteenth award is currently being negotiated and is expected to be funded in 1988.

Question. Are there institutions that have approved grants, but are not yet funded? If yes, why?

Answer. We presently have five approved, unfunded supplemental grant applications. Two additional applications currently under review are supplements, and one other is a new application. These pending applications are being considered for funding in 1988. The program has $11,010,000 available in 1988, from which to fund these applications. Funding decisions will be made based on the relative scientific merit of each application, as judged by peer review, and awards will be made to the extent that funds are available.

## NEW ORGANIZATION

Question. Dr. Ada Sue Hinshaw has been the director of NCNR for nearly one year now. Currently, is the institute adequately staffed to carry our its function, or will there be additional staff hired?

Answer. The President's request for FY 1989 would maintain NCNR staffing at 28 FTEs, the same level as FY 1988. Should NCNR programs continue to grow as they have during NCNR's two-year existence, staff must grow accordingly to ensure effective management.

Question. If additional staff is needed, what positions will be filled?

Answer. The need for additional staff would be generated by growth in the NCNR's programs, such as expansion of the nursing research grant portfolio and additional research training awards to advance towards the levels recommended by the National Academy of Sciences. The Center is developing a National Nursing Research Agenda with the assistance of outside experts. Already, two high priority research areas -- nursing care for AIDS patients and for low birth-weight infants -- have been identified and others will emerge soon. Therefore, if additional FTE's were made available to NCNR in FY 1989, our highest priority positions would include: two Health Scientist Administrators; a Grants Management Specialist; a Program Planner; a Program Analyst; a Budget Analyst; and a Secretary/Clerk to support above positions.

## EXTRAMURAL RESEARCH

Question. It is our understanding that in the less than two-year period of NCNR's existence there have been three specific areas of notable achievement. One involves determining risk factors that can predict the development of pressures or bed sores in the elderly; another relates to sleep disorders in some women;

and the third relates to urinary incontinence associated with the aging process. What are some of the other research areas being addressed by the institute?

Answer. Other areas being addressed by NCNR include oxygenation during acute illness for adults and neonates, recovery rehabilitation in chronic disease, and promotion of health behaviors in pregnant women.

Question. What is the status of these efforts?

Answer. The oxygenation studies are beginning their second year. It is too early to tell which techniques and procedures are optimal for adequate oxygen delivery, effective removal of secretions, and minimizing hypoxemia during endotracheal suctioning. Studies of recovery and rehabilitation following myocardial infarction, cardiac surgery, and hip fracture are also in early phases of development. These ongoing projects are exploring physiological and psychological parameters associated with chronic illness. Several studies that focus on health behaviors of pregnant women are in the second and third years of funding. For example, one study has addressed correlates between health behaviors and prenatal care to and birth outcomes. Another study examines biochemical and psychosocial factors related to postpartum depression symptoms. Replication studies and continuations of several promising studies are planned.

Question. Are there seemingly any breakthroughs forthcoming in any of these research areas?

Answer. Building depth in the science for nursing practice is a major commitment of NCNR. Although there is good progress in a number of areas of research, it is too early to expect definitive results. Replication studies are needed in order to provide the basis for new approaches to nursing care.

Question. For FY 1989, you are requesting a total of $18.66 million which is $879,000 more than for FY 1988, for 129 research project grants. What are some of the research areas to be explored through these grants?

Answer. Of the 129 research project grants, 45 are projected to be new competing grants and 84 will be noncompeting research projects. The NCNR expects to fund new grants in the area of prevention and care of low birth weight babies and changing health behaviors of pregnant women. Another related area of research is health promotion and disease prevention targeted to vulnerable groups.

Question. Will this funding go to support the continuation of any projects already underway or will funding be only for new projects?

Answer. Funding to support noncompeting continuation projects will include such as those cited above as well as those addressing nursing resources and quality patient care. This includes the special initiative on innovative nursing care delivery models and projects related to early discharge and home care.

## AIDS RESEARCH

Question. We understand that NCNR's AIDS-related research activities would be to encourage investigators-initiated research designed to encourage AIDS prevention and improve ways for providing nursing care to critical and long-term AIDS patients. The first NCNR AIDS research award was to be given during FY 1988. Has the research award been given to date?

Answer. The first AIDS project the Center intends to support this year is a project administered by the National Institute on Mental Health, with a nurse scientist as Principal Investigator. The decision to award has been made and an agreement with the NIMH for the co-funding has been completed. The actual award will be made very soon. At least three other projects will be funded after the June NCNR Advisory Council meeting.

Question. If so, what is the specific focus of the project?

Answer. The study funded with NIMH, "HIV Antibody Testing: Developing Guidelines for Screening Perpetrators of Victims of Sexual Abuse", addresses the critical need to detect HIV infection which has occurred in victims of sexual abuse, in order to begin medical treatment as soon as possible. Guidelines will be developed to address this subject, as well as the testing of the sexual perpetrators. Two other studies focus on HIV positive infants. Nursing interventions in the provisions of home care to HIV positive infants, infants physical and developmental status, and the mother's physical and emotional status are some of the variables to be tested.

## COLLABORATIVE RESEARCH PROJECTS

Question. We are aware that NCNR has been collaborating and co-funding specific research projects with other agencies, such as the National Institutes of Child Health and Human Development (NICHD) and the National Institute of Aging (NIA). What are some of the research projects you are co-funding with NICHD?

Answer. The NCNR has co-funded four projects with the National Institutes of Child Health and Human Development. The first three are with the Multi-Center Network of Maternal-Fetal Medicine Units. This network serves to identify priority areas of research in the field, and create opportunities for collaborative research between medical and nurse scientists in several locations. Nurse PIs are involved in studies of glucose levels and neuro-behavior of post-term babies, and the development and testing of assessment tools to predict complications of pregnant women who go beyond 42 weeks gestation. The NCNR contributed $65,762 to this network in 1987.

Another project which the NCNR co-funded with the NICHD is a Small Business Innovation Research study entitled "Cry Analysis as a Screen Test for Sudden Infant Death Syndrome and Handicap." The investigator seeks to capitalize on early observations of unusual patterns of crying which sometimes characterize infants who are handicapped or are susceptible to SIDS, and to develop a screening method for early identification of these infants. The Center contributed $66,000 to this project.

Question. Discuss some of your cooperative research efforts with NIA.

Answer. NCNR is collaborating with the National Institute on Aging to support multi-center clinical trials on behavioral methods of controlling urinary incontinence. This condition is often the primary cause for elderly persons to be placed in nursing homes, causing considerable distress and expense to the patient and family. The investigators are studying the applicability and rates of success of several behavioral methods recently developed, to lessen the occurrence of incontinent episodes. The NCNR contributed $366,052 to these clinical trials in FY 1987.

The NIA and NCNR are interested in identifying mechanisms for nurse scientists to work with the Alzheimer's Disease Research Centers on nursing care studies. We are also planning an initiative on self care and injury prevention of the frail elderly.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### BUDGET REQUEST

Question. Dr. Wyngaarden, what was the original budget request submitted to the Public Health Service Budget Office for NIH for FY 1989? How does this compare to the President's request?

Answer. The original FY 1989 budget request submitted to the PHS was $8,416,026,000, which included $565,209,000 for AIDS research. The FY 1989 President's Budget is $7,122,837,000, including $587,630,000 for AIDS.

Question. How many FTEs did you request? How does that compare to the President's request?

Answer. The request to PHS included 13,500 FTEs, while the President's Budget contains 12,902.

Question. What would an NIH current services budget be for FY 1989?

Answer. The NIH calculated current services budget for FY 1989 would be $7,606,443,000; with AIDS included at the 1989 President's Budget level of $587,630,000, the figure would be $7,654,261,000. The amount calculated by OMB within the terms of the Bipartisian Budget Agreement would be $6,774,593,000, or approximately 2 percent over current funding levels.

### RESEARCH TRAINING

Question. Dr. Wyngaarden, as you know, I have been very concerned about the need to provide adequate funding for research training. How much training money is requested for FY 1989?

Answer. The request includes approximately $240 million for research training in FY 1989, exclusive of AIDS research training funds.

Question. How does that compare with FY 1988?

Answer. Funding for research training in the FY 1989 request represents a 2-percent increase over FY 1988.

Question. Will the FY 1989 amount expand the research training program or will it remain essentially at the FY 1988 level? Explain.

Answer. The research training program will essentially remain at the FY 1988 level.

## CLINICAL TRIALS

Question. How much would you need to fund all the approved clinical trials?

Answer. For FY 1989, the total projected cost for major new clinical trials ready to begin but unfunded is $160 million.

Question. What would your FY 1989 current services budget be for clinical trials in FY 1989?

Answer. The NIH calculated current services estimate for all clinical trials would be approximately $500 million. The level calculated by OMB within the Bipartisan Budget Agreement would be $481 million.

## 1990 BUDGET

Question. Dr. Wyngaarden, this year the entire Department of Health and Human Services has submitted budget requests for 1989 and 1990. It is unclear to me why a 2-year budget was submitted and it is certainly an issue. Nevertheless, the NIH budget request includes a 1990 figure that is a 1.9-percent increase in non-AIDS NIH research over the 1989 request. I find it interesting that in 1989 a 5.4-percent increase in non-AIDS research is proposed, yet in 1990 only a 1.9-percent increase is requested. Do you think we will need fewer research dollars in 1990 than in 1989?

Answer. No, I do not think that we will need fewer research dollars in FY 1990 than FY 1989. The 1.9-percent increase for NIH programs is a reflection of the budgetary constraints necessary to reduce the Federal deficit.

Question. Will a 1.9-percent increase prove anywhere near a current services level (assuming you receive at least the President's request in 1989)?

Answer. The NIH calculated current services level for FY 1990 would be about $7.5 billion, or 14.5-percent above the FY 1989 request. The level calculated by OMB within the Bipartisan Budget Agreement reflects the 1.9-percent increase.

Question. What effect do such "see-saw" budget requests have on research and the research scientists who need to plan on a certain level from year to year?

Answer. The NIH and the research scientists we support would be required to adjust plans and priorities to achieve the goals of deficit reduction. Every effort would be made to minimize the impact on the research effort.

## OMB APPORTIONMENT

Question. Dr. Wyngaarden, last October the Director of the Office of Management and Budget wrote to me indicating that if a minimum number of new and competing grants was not specified in bill language, OMB would permit the resumption of 18 separate appropriations-based apportionments. As you know, the FY 1988 Labor-HHS Bill did not include a specified grant number (although one was included in report language). Has OMB allowed separate apportionments?

Answer. With the numbers of competing research projects to be funded by NIH removed from the language of the appropriations bill, the OMB has allowed the NIH to return to the more traditional apportionment process; that is, apportionment by appropriation rather than at the NIH level.

Question. Are there currently any problems with how NIH funds are apportioned?

Answer. We are experiencing no problems with the current apportionment method.

Question. Do you anticipate any apportionment concerns in FY 1989?

Answer. We do not expect any problems with apportionment procedures in the coming year.

## FUNDING LEVELS

Question. Dr. Wyngaarden, are we funding grant awards at their fully recommended level?

Answer. In FY 1988, downward negotiations are necessary.

Question. At what percent are grants funded?

Answer. In non-AIDS research, downward negotiations are averaging 7.4 percent for noncompeting awards and 11.1 percent for new and competing awards.

Question. Will any of this change under the President's Budget request?

Answer. We estimate downward negotiation at 10 percent for noncompeting and 13 percent for new and competing awards at the FY 1989 request level.

## RESEARCH CENTERS

Question. Dr. Wyngaarden, your budget justification indicates that the FY 1989 budget request for research centers will fund 556 research centers, 3 less than 1988. Will you have to terminate funding for 3 centers or will you be able to fund 3 new ones?

Answer. The reduction is necessary in centers currently funded by the National Institute of Child Health and Human Development (NICHD). NICHD expects to fund 44 centers for approximately $29,113,000 in FY 1988. Support of the same number of centers in FY 1989 would necessitate negotiated funding reductions of approximately 22 percent. The Institute believes that reductions of this magnitude would severely jeopardize the research conducted at these centers. Therefore, the NICHD would limit its support to 41 centers with negotiated reductions of approximately 16 percent.

Question. Either way, how will this cut be made? What centers will not be funded?

Answer. Of the 44 NICHD centers mentioned above, 10 will be competing for renewed funding in FY 1989: 3 in the mental retardation center network, 4 in the reproductive sciences, and 3 in the demographic and behavioral sciences. Since renewals are based on merit competition, we cannot say at this time which centers will not be funded.

Question. Are the existing centers fully funded at their recommended level?

Answer. The NIH, in the aggregate, is expected to have negotiated reductions of approximately 9.3 percent in the centers program in FY 1988 and approximately 12.3 percent in FY 1989.

## THIRD-PARTY REIMBURSEMENT

Question. Last year I asked about the impact of third-party reimbursement on the funding of research centers. How have these reimbursements or the lack of them affected the centers since you were last here? Is there still a problem?

Answer. Of the several types of centers supported by NIH, third-party reimbursements help offset the cost of operating the General Clinical Research Centers (GCRCs) funded by the Division of Research Resources. The number of research patients for whom it is appropriate to bill third-party insurance carriers continues to decline. As a result, a greater portion of all hospital costs are paid through GCRC appropriated dollars.

Question. What impact does this situation have on the funds needed by the research centers?

Answer. If the pattern continues, a greater portion of research patient days will be dependent on funding through GCRC appropriated dollars.

## 1989 BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. NLM's original request to the NIH Budget Office was $123,134,000 which was our professional judgment level as recommended by the Board of Regents Long Range Plan.

Question. What was the Department's original request to the OMB?

Answer. The Department's original request to the OMB for NLM was $66,771,000.

## FTE's

Question. What was the original FTE request to the NIH Budget Office?

Answer. NLM's original FTE request to the NIH Budget Office was 617 which corresponds to our professional judgment level of $123,134,000.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. NLM's FTE level under the 1989 President's Budget is 499.

## MEDLINE KNOWLEDGE FINDER

Question. I understand that the Association of Academic Health Sciences Library Directors and Medical Library Association strongly support the development of a MEDLINE Knowledge Finder which would provide online textbooks in a hypertext environment. Are there any efforts at the NLM to develop such a capability?

Answer. Yes. In our Online Reference Works program we are exploring how best to bring medical reference works (textbooks) into an online environment. This effort includes investigations into data structures that would best support the hierarchical structure of textbooks and the non-linear structure to support hypertext-like linkages. Two examples of this work include Mendelian Inheritance in Man, an online textbook of human genetics by Dr. Victor McKusick at Johns Hopkins, and Principles of Ambulatory Medicine, a textbook of general medicine also written at Johns Hopkins.

In addition, a collaborator in NLM's Unified Medical Language System is Dr. Robert Greenes at Brigham and Woman's Hospital in Boston. He too is using hypertext techniques to deal with medical vocabulary in relation to literature retrieval and patients' medical records.

Question. I am told that it would cost approximately $6 million to develop such a system. Do you agree with that figure?

Answer. This is about the correct estimate of costs for such a research and demonstration project in a single well-defined medical domain. It would not be an appropriate figure for creation of a final product or a system that deals with all of clinical medicine.

Such work benefits from close collaboration between biomedical subject matter experts and technically skilled computer scientists. This takes time. In addition, such work benefits greatly from independent research in related fields. Thus, consistency and constancy of funding of such a project over time may be even more important than the final total amount of funding.

## BIOTECHNOLOGY

Question. Dr. Lindberg, are you receiving applications from universities and companies for support of research in developing information systems in Biotechnology?

Answer. Yes, we have received and evaluated 36 applications during the last year for research in developing advanced information systems in Biotechnology.

Question. What percent of these applications will you be able to fund of the approved applications?

Answer. Twenty percent of the applications can be funded. We hope to apply $1 million to this category of proposal.

## AIDS

Question. The Library is the only part of NIH that does not have money in its budget designated for work relating to AIDS. Is the vast and growing literature on AIDS being adequately controlled through existing channels of biomedical information technology?

Answer. Information about the AIDS literature is fragmented among many different databases. A substantial portion of the scientific AIDS literature published in biomedical journals and books is covered in MEDLINE, CATLINE, and other biomedical databases. Articles from newspapers and magazines on related social, economic, legal, and political issues are covered in online magazine and newspaper indexes. Factual information about AIDS research protocols appear in the National Cancer Institute's PDQ (Physician's Data Query System). While the combined coverage of AIDS literature in these disparate databases is extensive, access to the totality of the pertinent information is time-consuming and difficult and the extent of any gaps in coverage is hard to determine.

## BUDGET REQUESTS

Question. What was the original request to the NIH Budget Office?

Answer. The FIC's original budget request to the NIH Budget Office, for FY 1989, was $15,748,000.

Question. What was the Department's original request to the OMB?

Answer. The Department's request to OMB for the FY 1989 FIC budget was $11,257,000.

## FTE'S

Question. What was the original FTE request to the NIH Budget Office?

Answer. The FIC's original request to the NIH Budget Office for FY 1989 FTEs was 62.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The number of FTEs for the FIC reflected in the President's Budget represents a change from 62 to 57.

## HEALTH RESEARCH STRENGTHENING

Question. Dr. Kupfer, I have always felt that the best kind of aid we could provide to the people of Central America and elsewhere in the world was our expertise in the delivery of health care and biomedical research. What is the Fogarty International Center doing to strengthen health research through international collaboration and research training?

Answer. The FIC's mission statement includes the directive to facilitate the assembly of scientists and others in the biomedical, behavioral, and related fields for discussion, study, and research relating to the development of health science internationally. Several FIC extramural activities currently support this initiative. The International Research Fellowship (IRF) Program provides advanced research training opportunities to foreign scientists, who, upon returning to their home country, contribute to their scientific community by continuing their advanced research careers. The Senior International Fellowship (SIF) Program supports established U.S. scientists to conduct collaborative research activities abroad while contributing to the exchange of scientific information internationally. The Scholars-in-Residence (SIR) Program allows eminent U.S. and foreign scientists to interact with the NIH research community through conferences, seminars, and lectures involving advanced health research topics, and to contribute to the exchange of scientific information when they return to their home institution.

Another FIC program that contributes to the strengthening of biomedical research internationally and facilitates international scientific collaboration is the International Coordination and Liaison Program (ICLP). The ICLP serves as the link between the NIH and other governments and institutions, coordinates activities of 67 bilateral agreements involving 39 countries, and provides the administrative management for the Public Health Service Health Scientist Exchange and the NIH Biomedical Research Exchange Programs.

Finally, in its role as a WHO Collaborating Center for Research and Training in Biomedicine, the FIC has been working closely with the Pan American Health Organization (PAHO) to strengthen north-south collaboration in health research in areas of mutual benefit. A recently completed project involving leading scientists, health administrators and policy makers in the United States, Argentina, Brazil, Chile, Costa Rica, Mexico and Venezuela led to recommendations on how international collaboration can strengthen research on major epidemic and endemic diseases.

Question. What is the Center doing in the area of AIDS and how do you coordinate such efforts with other Institutes who are involved in international AIDS activities, such as the National Institute of Allergy and Infectious Diseases?

Answer. The Senate Report language accompanying the FIC 1988 AIDS appropriation contained specific guidance for supporting expanded international research on AIDS. Accordingly, the FIC has initiated two new award programs: the Special International Postdoctoral Research Program in AIDS, and the International Training Grants in Epidemiology Related to AIDS. The FIC's expanded efforts in AIDS research has involved extensive discussions with the NIH Director and the Directors of the National Cancer Institute and the National Institute of Allergy and Infectious Diseases. The FIC is also supporting the critical process of AIDS information exchange through its conference initiatives and involvement in the IV International Conference on AIDS, the Second International Conference on Antiviral Research, and the Pan American Conference on AIDS in Guadalajara.

## 1989 PRELIMINARY BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. DRR's original request to NIH was $477,454,000, which excluded funds for AIDS research.

Question. What was the Department's original request to the OMB?

Answer. The Department's request for DRR to the Office of Management and Budget (OMB) was $254,968,000 without AIDS funds.

## FULL TIME EQUIVALENT EMPLOYMENT

Question. What was the original FTE request to the NIH Budget Office?

Answer. Our original request to NIH was for 102 FTEs in 1989, 98 of which were for non-AIDS activities, and 4 were for support of AIDS research activities.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The 1989 President's Budget requests a total of 99 FTEs for DRR, 89 of which are for support of non-AIDS activities, with the remaining 10 being for support of AIDS research activities. This represents a reduction of 9 non-AIDS FTEs from the original request, and an increase of 6 AIDS FTEs to administer the increased new AIDS program activities in the Division for which funds have been appropriated in 1988. This results in a net reduction of 3 FTEs from the level of 102 FTEs that we had originally requested in our preliminary submission to NIH.

## NATIONAL CHIMPANZEE BREEDING AND RESEARCH PROGRAM

Question. Dr. Pickett, I understand there is some concern about whether or not we have and will in the future have enough chimpanzees needed for AIDS vaccine research. Would you please comment on this situation, and will the National Chimpanzee Breeding and Research Program be able to respond to this growing need?

Answer. There is concern about the supply of chimpanzees needed for AIDS research. At present, no protocols are being cancelled or delayed because of a lack of chimpanzees. The animals used at this time are selected from those that have already been used in hepatitis B research. The PHS AIDS Animal Models Committee reviews all Federally-funded AIDS protocols requiring chimpanzees, in order to keep the numbers used as small as possible. Our experience with the development of the hepatitis vaccine indicate that more animals will be needed than are presently known to be available. Other than importation from Africa, which is not likely to be allowed, the only hope for obtaining additional animals is through the National Chimpanzee Breeding and Research Program. In fact, it is the only activity known to us that will assure U.S. researchers in the twenty-first century of the availability of chimpanzees for research. This program is expected to produce 60 chimpanzees per year. We expect to maintain a breeding stock of approximately 350 mature animals. Thus, we feel the Program will be adequate and will be able to respond to the future need for additional chimpanzees.

## FUNDING FOR BRSG PROGRAM

Question. Dr. Pickett, it came as a surprise to me this year that the Administration did not once again propose eliminating the Biomedical Research Support Program. I see, however, that a small reduction of $138,000 is proposed for FY 1989. In your professional judgement is this enough to maintain our commitment to funding new investigators and pilot research activities through this program?

Answer. Although the average award size will be reduced in 1989, the flexible nature of the BRSG awards will still allow institutions to determine locally how best to use these funds to further their biomedical research activities, and they will provide much needed support to continue funding new investigators and pilot research activities. In light of overall budget constraints, we feel this level of funding in 1989 will be adequate to maintain some of the more important functions that the BRSG program provides to the biomedical research community.

## ANIMAL FACILITY IMPROVEMENT GRANTS

Question. Dr. Pickett, what is the status of the NIH laboratory animal improvement program?

Answer. Laboratory Animal Facility Improvement grants assist biomedical research institutions in upgrading their facilities to meet required standards, Federal policies and regulations, and to develop effective, high quality animal care programs. These awards support the purchase of appropriate types of caging, sanitation equipment, and facility renovations. In FY 1987, 42 awards totalling $9.849 million were made. In FY 1988, 120 grant applications requesting over $44 million were received in response to a Request for Applications (RFA). We expect to make approximately 50 institutional awards from the $11.958 million appropriated for this program in FY 1988. This program has had a very positive effect on addressing institutional animal facility improvement needs.

Question. How much is included in the President's request for this program?

Answer. The President's FY 1989 budget request includes $11,958,000 for the Laboratory Animal Facilities Improvement Program.

Question. How does that compare to 1988?

Answer. The President's FY 1989 budget request of $11,958,000 for the Laboratory Animal Resources Improvement program is the same amount as in the FY 1988 appropriation.

Question. Are there other programs and funds included in the budget request designed to ensure careful and lawful compliance with animal facility requirements?

Answer. The FY 1989 budget request for DRR also includes $3.0 million for renovation and modernization of facilities at the seven Regional Primate Research Centers. These funds will be used for general improvements throughout the Centers' facilities and laboratories. A portion of these funds will be devoted to improvement of primate housing at the Centers.

The Public Health Service (PHS) Policy on the humane care and use of laboratory animals requires that all institutions using animals in sponsored programs submit regular assurances that their institution conforms to the Public Health Service Guide for the Care and Use of Laboratory Animals. In addition NIH makes periodic site visits and investigates allegations of improper care of laboratory animals. The Public Health Service policy also prescribes institutional committee review of each research protocol and twice a year review of their program. The NIH peer review process also take special note of the protocols using animals in each research proposal. The Department of Agriculture also inspects most laboratories using research animals in their enforcement of the Animal Welfare Act.

## RESEARCH FACILITIES IMPROVEMENT PROGRAM

Question. Dr. Pickett, in FY 88, Congress appropriated $23,935,000 for an extramural AIDS Research Facilities Improvement Program. How have these funds been able to address the facility needs related to AIDS research?

Answer. The Research Facilities Improvement Program was established in fiscal year 1988. At this time we are proceeding as quickly as possible to field the program for the repair, renovation, modernization and expansion of existing AIDS research facilities and for the purchase of associated equipment.

The awards will be made competitively. They will be in the range of $250,000 to $1 million. We will pay no indirect costs. There is no matching requirement. The eligible institutions are domestic non-Federal institutions or organizations which have active or pending PHS peer reviewed AIDS or AIDS-related research support.

The schedule is as follows: the pre-solicitation notice was published on March 4, 1988, the request for application was available on April 22, 1988, the deadline for submission of applications is July 15, 1988, the initial review is scheduled for early September 1988, the National Advisory Research Resources Council will convene on October 31, 1988, and awards will be made by December 1, 1988.

To date we have received more than 350 inquiries about the program and we expect to receive a significant number of applications by the July 15 deadline for submission.

At the hearings next year, after the awards have been made, we will be able to provide a more concrete answer as to how these funds have been used to address the facility needs related to AIDS research.

Question. How much does the President's Budget request include for this program in FY 89?

Answer. The FY 1989 budget request proposes that all AIDS funding be consolidated in the request for the Office of the Assistant Secretary for Health. No funds are included for the Research Facilities Improvement Program in the 1989 request.

## AIDS FUNDING IN PRIMATE RESEARCH CENTERS

Question. How much will we spend on primate centers for AIDS research in FY 88?

Answer. In FY 1988, $6,248,000 has been budgeted for AIDS research in the primate centers. Additionally, of the $23,935,000 appropriated for AIDS infrastructure within the Research Facilities Improvement Program, $2,872,000 will be devoted to the renovation of facilities used in the conduct of AIDS research at the primate research centers.

Question. How much is requested for FY 89?

Answer. DRR's budget request for FY 1989 does not include any funds for AIDS research. However, of the funds included in the 1989 AIDS request from the Office of the Assistant Secretary for Health, $12,835,000 is requested for AIDS research in the primate research centers.

## BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. At the time that the 1989 Preliminary Request to NIH was made, the NCNR requested a total of $30,459,000.

Question. What was the Department's original request to the OMB?

Answer. The Department's original request to the OMB for the National Center for Nursing Research was $17,804,000, excluding the AIDS research request.

FTEs

Question. What was the original FTE request to the NIH Budget Office?

Answer. At the time of the 1989 Preliminary Budget request to the NIH, NCNR was under a ceiling of 15 FTEs for 1988. The 1989 request was for 28 FTEs. That level was achieved in the current year, 1988, from support of NIH and the Department.

Question. How does that compare to the FTE allocation in the President's budget?

Answer. The President's Budget proposes that the Center be continued at the current staffing level of 28 FTEs.

NURSE TRAINING

Question. Dr. Hinshaw, since the National Center for Nursing Research was created to support research that will enable nurses to provide better care, doesn't it make sense that we will need to train nurses in the new nursing methods and approaches identified and developed at the Nursing Center?

Answer. It is critical that nurses understand the current information related to the biological, psychological and the behavioral sciences. New methods and technologies are developed continually, making it essential for nurses to have ready access to education and training. Programs to educate new nurses need to revise curriculums so that they prepare students for the demands of our future clinical settings. Nurses in practice need access to continuing education to further develop clinical skill. The Division of Nursing, Bureau of Health Professions, HRSA, has the mandate to address clinical training issues.

Question. Does it make sense to you, then, that the same administration that is requesting a $1.7 million increase in Nursing Research is also proposing to "essentially" eliminate all nurse training funds?

Answer. The nursing shortage is a complex problem. It is unclear whether the problems being experienced reflect a "current imbalance" or a "sustained shortage." We do know, however, that the aggregate number of nurses is at its highest, but excess demand for nurses persists in hospitals and nursing homes. The NCNR and the Division of Nursing, Bureau of Health Professions, HRSA, are planning to support a research and demonstration project of innovative nursing care delivery models. This project will address variables such as establishing work environments conducive to professional practice including shift work, wages and benefits, clinical roles of nurses and resources needed to provide quality care. The Secretary's Commission on Nursing is also making recommendations for the public and private sectors to address problems in providing the necessary nursing care in all settings: hospitals, nursing homes and home care. Hopefully, productive strategies for utilizing scarce resources, whether federal, state, or private, will be identified. Finally, while we understand the President's 1989 budget request for HRSA includes a reduced request for health professionals training, we also understand that nursing is one of the five areas of emphasis in the streamlined program.

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### SUBCOMMITTEE RECESS

Senator CHILES. The subcommittee will stand in recess until tomorrow morning at 9 o'clock. Then we will meet again in SD–192 to hear the following Institutes of the National Institutes of Health: Cancer, Allergy, Dental, Heart, Aging, and Eye.

[Whereupon, at 11:21 a.m., Tuesday, April 26, the subcommittee was recessed, to reconvene at 9 a.m., Wednesday, April 27.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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WEDNESDAY, APRIL 27, 1988

U.S. Senate,
Subcommittee of the Committee on Appropriations,
*Washington, DC.*

The subcommittee met at 9 a.m., in room SD–192, Dirksen Senate Office Building, Hon. Lawton Chiles (chairman) presiding.

Present: Senators Chiles, Bumpers, Weicker, and McClure.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

**STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH**

**ACCOMPANIED BY:**

**DR. VINCENT T. DEVITA, JR., DIRECTOR, NATIONAL CANCER INSTITUTE**

**DR. ANTHONY S. FAUCI, DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES**

**DR. HARALD LÖE, DIRECTOR, NATIONAL INSTITUTE OF DENTAL RESEARCH**

**DR. CLAUDE LENFANT, DIRECTOR, NATIONAL HEART, LUNG, AND BLOOD INSTITUTE**

**DR. T. FRANKLIN WILLIAMS, DIRECTOR, NATIONAL INSTITUTE ON AGING**

**DR. CARL KUPFER, DIRECTOR, NATIONAL EYE INSTITUTE**

**DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY, DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### QUESTIONING BY SENATOR McCLURE

Senator McClure [presiding]. This morning we will continue our NIH hearings and focus on the institutes that deal with cancer, heart, dental, allergy, and infectious disease, and aging.

Senator Chiles has been unavoidably detained. And since he knew I had some questions on a peculiar, relatively focused nature, it was suggested that I go ahead and get that done, pending his arrival, and the broader inquiry and questions that the committee will make. And I appreciate the chairman's accommodation to both you and to me.

We can expedite what the committee's deliberations this morning will be. Dr. DeVita, I want to publicly thank you for having convened a peer panel to review the boron neutron capture therapy proposal at the Idaho National Engineering Laboratory.

Dr. DeVita. You are quite welcome.

### BORON NEUTRON CAPTURE THERAPY

Senator McClure. And that report is in and in some respects I guess some of us were more optimistic. We are disappointed, but nevertheless, it is not totally negative. I assume that you are familiar with that report.

Dr. DeVita. I am.

Senator McClure. One of the things that I need to try to understand is, the report indicated that it was unlikely that, due to the remoteness of the facility, it would be possible to conduct clinical trials at that location.

Can you explain to me a little further why that conclusion was arrived at?

Dr. DeVita. Yes; the proposal itself contained a protocol for the treatment of patients with glioblastoma multiforme, a form of brain tumor. If the clinical trial was going to be run entirely out of that facility, then that facility or a nearby hospital would have to be set up to do a clinical trial which would require all the usual staff and monitoring capabilities, and the capacity to attract patients.

In the United States, there are probably only 1,000 or so patients with that diagnoses. This is a very small number of potential patients. In our experience remote facilities have a hard time attracting patients.

On the other hand, that is not the only clinical trial the facility could be used for. When we discussed the issue of boron neutron capture, we had in mind other kinds of clinical trials that we think this facility could participate in as one member of a group, as opposed to the entire clinical trial being run out of that single facility.

Senator McClure. I do not think there is any question that the National Engineering Laboratory is not currently in the business of running trials of that kind. And I do not believe that they have ever thought that they could do it all by themselves. That is why they have reached out to experts and a lot of different disciplines at various locations.

I guess the thing that is puzzling to me is, is the conclusion that you cannot run a clinical trial there? I understand your answer to be that obviously they do not have the facilities at the present time to run a clinical trial all by themselves.

Dr. DeVita. Correct. We hope that they will modify that proposal and become more interested in trials for malignant melanoma, the malignant moles that metastasize to the brain.

At the moment although we have a handle on all the other phases of the disease, many patients die with brain metastases. And we see boron neutron capture therapy as a way of getting around this. BNCT is very dependent on chemicals that actually concentrate in the tumor and we have chemicals that do that for melanoma.

We had initially thought that when the Idaho facility made their proposal they would include that kind of study, and they have not. I think there is some hope for readdressing the issue and coming back in with a different proposal.

Our radiation research program has a meeting set up in Annapolis on the 3rd and 4th of May to bring the three major groups together to discuss plans for protocols for refurbishing machinery so that we can get some data on the boron neutron capture technique.

## SELECTIVE COMPOUNDS

Senator McClure. I notice that the report is not overly critical of Dr. Hatanaka's work in Japan. But they are less optimistic about it, I guess is the best way to put it. Less sure of the results that he is obtaining than others have been.

Dr. DeVita. And I share that, because I think that we do not have enough information to suggest that the compounds that Dr. Hatanaka has will actually go into brain tumors selectively.

You must get compounds into the tumors selectively, because the radiation beam is very damaging to brain tissue and we do not want the normal tissue to accumulate the chemical.

For the tumor I mentioned, melanoma, we have compounds that are put into the machinery of the melanoma cell so that we can very comfortably get enough boron in to use BNCT as a therapeutic tool.

## PI MESON CLINICAL TRIAL

Senator McClure. Well, I know the difficulty you had at one earlier time, one of the panel members that I recall was involved in attempts to use the pi meson.

Dr. DeVita. Correct.

Senator McClure. And was unable to recruit the patient load necessary in New Mexico in order to conduct a clinical trial there.

Dr. DeVita. That is true. They were running the clinical trial solely out of Los Alamos. And I think they put 322 patients on over a decade at a cost of some $22 million.

It was not feasible, although it was the only pi meson facility available, and building new pi meson facilities is extraordinarily expensive. The choice had to be made not to go forward with that, and to let other facilities be built elsewhere in the world.

I think this is different, though, and I am quite optimistic about the capacity to treat this way. I think we need to show whether or not it will be effective.

We do not need to say that forevermore patients would have to go to INEL to get it. If we can prove that this is a useful way of dealing with brain metastases, then we can expand the program in other ways.

So I hope we will be able to convince INEL to come in with a different kind of proposal, and proceed.

### UNIQUE GENERATOR OF EPITHERMAL NEUTRONS

Senator McClure. I guess one of the reasons that I press forward to try to find some way is that there is no place else in the world that has a generator of epithermal neutrons in quite the same way as this facility.

It was built for other reasons, it was not built for this purpose, and would never have been built for this purpose. As a matter of fact, I suppose the expense would indicate that no other one like this will ever be built for this purpose.

It has been suggested that we might be able to get epithermal neutrons from accelerators, as a derivative product in the accelerator, and with reaction. But that is extremely expensive.

Dr. DeVita. Yes.

Senator McClure. If we are going to have any research at all of the efficacy of epithermal neutrons in the treatment of any class of cancers, it is pretty likely to occur where the generator of those neutrons is located.

Now, there are other low-level generators of epithermal neutrons, and certainly there are other neutron sources. But there is none like this one. And it stands in great risk of being decommissioned.

Dr. DeVita. I understand, yes.

### FACILITY CONVERSION ON HOLD

Senator McClure. It costs somewhere on the order of $2 million a year just to hold the reactor in standby, which is not an inconsiderable amount of money.

The recommendation of the panel is, hold this facility in cold standby for 5 years while we try to determine whether or not it can be used. I think that is——

Dr.DeVita. That is what they recommended, yes.

Senator McClure. While other work is done to determine whether or not it would justify human clinical trials.

And I think almost—the negative parts of the report are, do not convert the reactor now, we are not sure we can use it for human clinical trials. And the second is, do not go forward with planning any human clinical trials until we know more about the compounds and their reactions. Is that not a fair summary?

Dr. DeVita. Correct.

Senator McClure. The other preliminary work, most of the other preliminary work with respect to the boron compounds, their physiological effects, can be conducted in a variety of different places in the existing and planned experimental activities, and most of those other activities are approved by the report.

Dr. DeVita. Yes.

### PEER REVIEW OF FACILITY

Senator McClure. So there must be at least some level of expectation—maybe hope is the right word, but I would like to think maybe it is a little bit more than that—expectation that growing out of this research over the next 5 years we will be better able to make a decision as to what the prospects are. Is that a fair reading of the report?

Dr. DeVita. Yes; you should consider the report, I certainly do, as advisory, not a final decision. This was not a grant application to the Cancer Institute. The review was arranged by NCI in response to a request from DOE for us to help them out. I do not think we have to wait 5 years to decide whether or not we should have the reactor converted. I think by the meeting in May this question can be addressed, and we can determine whether or not we should go ahead and do it.

There are two other competing reactors in the country. One at MIT and one at the Brookhaven National Laboratories, both of which are OK but in some ways are not as good as the INEL reactor. But they are near major metropolitan centers with hospital facilities. So there will be some discussion about the relative merits of each, and you can imagine those institutions would like to have their reactors upgraded.

Senator McClure. Oh, yes. I understand that.

Dr. DeVita. I think that the site visitors did a good job in assessing the basic qualifications and so forth, but they were not asked to look at the national planning for this project. We are doing that. And I will not accept all their recommendations as being absolute without some further discussion.

### COST OF CONVERSION

Senator McClure. Well, if we are to hold that in abeyance for 5 years, and if the standby costs are around $2 million a year, we have invested $10 million. That compares just in gross dollars relatively equally with conversion costs.

Dr. DeVita. Correct.

Senator McClure. So we could right now at about the same cost convert the reactor and have it converted and ready to use, but I recognize too that you might do that and then decide you cannot use it anyhow, and you would have wasted the conversion costs and still have the decommissioning costs.

But that conversion cost is relatively the same amount of cost as to hold it in standby for 5 years.

Dr. DeVita. Well, Senator, the nature of research is that there is a bit of a gamble involved in all of it. We do not know that boron neutron capture will, in fact, be a big advance. However, some of us think it is very worthwhile trying for a specific tumor that we think really needs to have some additional therapy developed. This is not that much of a gamble in the context of the amounts of money we spend on research.

My feelings are we should try to make use of it. But I think we should wait until this early May meeting and see what the other scientists have to say about where we go and how we do it.

### PARTICIPATION IN NATIONAL PROGRAM

Senator McCLURE. I guess it is fair to say that if this facility had not already been constructed for other reasons, if it did not already exist we would not contemplate creating it.

Dr. DEVITA. I think not. Because we would like to be able to be near where patients usually go.

But again, I submit to you that I think that the best use of the facility is not for them to independently run their own clinical trials but to be part of a program that is a national program where they do one piece of the therapy.

And then you have a problem of taking patients to Idaho and putting them in a very fine facility that is only about 60 miles away, and having them travel daily to get their treatment for that piece of it, and then taking them back to where the main clinical trial is run.

Inconvenient? Yes; not something you would want to do as a routine for all patients with that disease, but to prove or disprove the point that it is an effective way of approaching the disease, quite adequate for an experiment.

The people at INEL did not apparently agree with that at first, and so that is why they came in with a proposal for brain tumors of a different type that we were not terribly enthusiastic about, nor was the site visit group.

### PATIENT BENEFIT

Senator McCLURE. Well, it is certainly inconvenient for a patient to travel in that way tohave treatment in that manner. But it is better than dying.

Dr. DEVITA. For those patients, it would be the only other choice to dying.

Senator McCLURE. And I think the survival rate for that kind of cancer is fewer than 5 percent live more than 1 year.

Dr. DEVITA. For metastatic melanoma to the brain, prognosis is truly bad. You may be referring to glioblastomas, but I am thinking, again, about metastatic melanoma.

The good thing about metastatic melanoma is that we can control the disease outside the brain. But we lose the patients because the cells migrate to the brain and kill the patient as a brain tumor does. So that for both populations, it would be a major advance.

We are a bit ahead of the game in melanoma because the Japanese scientists have already found the compounds that can be collected in the melanoma tumor. We do not have them, really, for the primary brain tumor.

### MELANOMA INCIDENCE

Senator McCLURE. And what is the incidence of the melanomas?

Dr. DEVITA. This year there will be 27,000 cases of melanoma, of which about 6,000 will die. Most of them are curable by simple means.

But the 6,000 who die, 80 percent die with brain metastases, even if they have their other disease controlled.

And we have a handle on that particular tumor in such a way that we think we can do a lot of things at the front end. We would like to be able to cover it from beginning to end, and the boron neutron capture therapy by Dr. Mashima has worked well on a few patients treated in Japan.

We had Dr. Mashima over to NCI to talk to him about his work, and I must say I was quite impressed with what he was doing. And that is how really we got involved in this.

## PATIENT ACCRUAL FOR PI MESON TRIAL

Senator McClure. I am a little puzzled to know why you had the experience you did with the pi meson experiments and why you had difficulty getting people to go to New Mexico for treatment.

We have people that have the glioblastomas that are traveling to Japan for treatment. No matter how remote Idaho may be, it is not that far.

Dr. DeVita. The pi meson issue was a question of whether pi mesons were better than standard x rays for a whole variety of tumors. Pi mesons have the capacity to deliver the radiation dose right into the tumor, as opposed to the surrounding tissue. It is a very precise way of radiating.

The issue was can you do better than standard x rays. So it required a test in a variety of fairly standard tumor situations. The patient population just was not available out there, and you certainly could not just run air flights out of patients——

## ALTERNATIVE THERAPIES

Senator McClure. I think you get alternative treatment at other locations.

Dr. DeVita. That is right. They could get alternative therapies that work. In fact, pi meson-treated patients would be compared to an alternative therapy in a controlled trial. That is where the clinical trials expertise becomes very important, and that is what they do not have at INEL and would have to acquire if they were going to set up that kind of a trial.

But, in my own view, that kind of a trial is not the right way to use the INEL. But this will all come out in May.

## GLIOBLASTOMA THERAPY

Senator McClure. Well, the glioblastoma patients really have very little alternative.

Dr. DeVita. They do. Again, I want to emphasize, however, that I am not very enthusiastic that this method will work, until we have a better chemical compound to use in glioblastoma patients along with the machine.

There are other experimental alternatives that we have——

Senator McCLURE. I understand that. I just mention that because that is the one that has attracted the initial attention and what the public comment is about.

And it is also the patients that are traveling to Japan who receive treatment in Japan, at least one of whom is back in her home community, and apparently having recovered from the treatment she received in Japan. Apparently, because you would know the uncertainties better than I, in that, and the way the public might interpret it.

But if this is indeed a fatal condition, the patients do not have very many alternatives, and they do grasp at straws, good ones and bad ones. If there is a process that might be made available that gave them some hope, there are a great many people in our body politic, in our society, that would say, well at least give them that hope, particularly where the facility already exists.

And while indeed you may well be right, and I have read the report and I read the uncertainties in the evaluations and critiques, no matter what the uncertainties might be, there is the alternative certainty and that is relatively swift death.

For some of us, we wonder why we have to permit that to happen when there is the possibility, as uncertain as it may be, the possibility of using this existing reactor to provide a treatment that gives some degree of hope to survival.

Dr. DEVITA. I agree with you. It is very frustrating under those circumstances not to have it. The way you phrase it is unarguable, and I think that people who desperately need something should have a chance to go for experimental therapies.

However, it is a matter of priorities, and I think the INEL reactor is unique and can be used effectively for other kinds of tumors. For glioblastoma at the moment, there are alternative experimental approaches that patients could receive with a better chance of success than the INEL boron neutron capture.

That was why I think the proposal got into a little trouble in this review. But that is not unique, Senator, in terms of the give and take in the peer review process. An idea comes in, peer review looks at it, criticizes it.

As a result, I understand from my staff that folks at INEL are redoing the proposal to include the other kinds of tumors that we will be interested in. So we might have avoided the problem, but that happens quite a lot.

Senator McCLURE. Well, that is the reason we asked for the evaluation.

Dr. DEVITA. You did a very worthwhile thing. And thank you for it.

Senator McCLURE. And I do appreciate your willingness to undertake that and to convene the panel so that the review could take place, because obviously we have nuclear physicists and chemists and so on at work at the Idaho National Engineering Laboratory. I do not think any of them pretend that that is the center of medical excellence in the treatment of tumors.

Dr. DeVita. No; but they have the finest engineering group of any of the reactors that might be competitive, so they should be quite proud.

### OTHER REACTORS AVAILABLE

Senator McClure. And they have a unique reactor. I think while we can say, yes, Brookhaven has a source of neutrons, so does the University of Washington, so do a number of other places.

I think Loma Linda just put in a radiation therapy center at the cost of $100 million for the source of materials. We, because of other priorities in the past, built a facility that is very unique.

And it is hard to compare it because the quality of medium-range neutrons, the epithermal neutrons, that are produced at the power burst facility is unmatched anywhere else in the world. It is not even comparable to what exists at Brookhaven or MIT at the present time.

Dr. DeVita. Yes.

Senator McClure. But again, it was built for different purposes. It would never be built for this purpose.

Dr. DeVita. I believe you are correct. And I am more inclined in the direction you are heading than the site visit report.

But you should view site visit reports just as that. They were asked to do a limited job, they did a really superb job. But we did not ask them to solve all the problems of the world, and that is our responsibility.

Senator McClure. Well, thank you very much for your testimony, Dr. DeVita.

Dr. DeVita. Thank you.

Senator McClure. I look forward to working with you on this project.

Dr. DeVita. Thank you very much, Senator.

### SENATOR CHILES' OPENING REMARKS

Senator Chiles [presiding]. This morning we will continue our NIH hearings, and we will hear from the Cancer Institute, with a request of about $1.5 billion, the largest Institute, followed by Heart, Lung, and Blood with a request of slightly over $1 billion.

The Dental Institute, which is celebrating its 40th birthday this year, is one of the great NIH success stories. The dental health of Americans has improved greatly over the last generation, and the Institute has led the way in the progress.

The National Institute of Allergy and Infectious Diseases conducts 53 percent of the NIH AIDS research, and offers Governmentwide leadership in this area.

Dr. Wyngaarden, we look forward to hearing from the several Institute Directors appearing before the subcommittee this morning. We would like to hear briefly the progress being made in each area and the highlights of the 1989 request.

If you will introduce your Institute Directors, then I think we will begin with Dr. DeVita of the Cancer Institute.

## INTRODUCTION OF ASSOCIATES

Dr. WYNGAARDEN. Thank you, Senator Chiles. With me today are Dr. Vincent DeVita, Director of the National Cancer Institute; Dr. Harald Löe, the Director of the National Institute of Dental Research; Dr. Anthony Fauci, the Director of the National Institute of Allergy and Infectious Diseases; Dr. Claude Lenfant, the Director of the National Heart, Lung, and Blood Institute; Dr. T. Franklin Williams, Director of the National Institute on Aging; Dr. Carl Kupfer, Director of the National Eye Institute; and Mr. Dennis Williams, from the Department.

Senator CHILES. Dr. DeVita?

Dr. DEVITA. Thank you, Mr. Chairman. I am pleased to be here to report on progress of the National Cancer Program. And if I may, I would like to submit my full testimony for the record, and just make a few comments.

Senator CHILES. It will. All your statements will be in the record.

Dr. DEVITA. Let me cover tw[illegible] areas. First, I will describe some of our unfolding knowledge of the bio[illegible] of the cancer cell.

There is a good deal of excitement this year about how we are beginning to understand why a normal cell becomes malignant.

When Mother Nature decided to make multicellular models, like us, with billions and billions of cells, she obviously needed some signaling devices so cells could communicate with one another.

We now know that the oncogenes that you have heard us talk about over the past 5 or 6 years here at hearings, are, in fact, genes that code for both the proteins that signal and the receptors that receive those signals for this very complicated series that appears to operate in a genetic cascade. Cancer basically turns out to be a genetic disease.

And this year there have been some very critical discoveries about genes that control this cascade. A new gene has been found that controls the metastatic process in cancer and suppresses it. This is very important since many people die from metastases.

The significance of these findings, I think, is the quiet certainty that is growing in the scientific community, that this cascade lends itself to interruption, and that the knowledge of this cascade should convert cancer from an unsolvable to a solvable problem.

And, in fact, there have been some practical applications of the molecular biology already, in diagnosis where these tools in the lab are being used to diagnose patients with lymphomas and leukemias. We now can determine the prognosis of patients with breast cancer and colon cancer and lung cancer by using these molecular probes.

You have probably read in the newspapers the patenting of the transgenic mice. For the first time we have a model we think will be the best way to focus prevention efforts. These mice have human genes that lead to a certain kind of cancer introduced into them and, can be used as a model to show how you can shut those genes down. So we are very excited about the implications of this for prevention research.

It has also been a very good year in the clinics, switching to a more practical level. In 1971, with the exception of surgery and radiotherapy for the common kinds of cancers, we had no other therapy for the 65 percent of the people who were presented with cancer outside the local confines of a lymph node or a primary tumor.

We now have a positive trial that reduces mortality within the study population for almost all of the major cancers. And this year we have had positive studies in colon cancer and rectal cancer.

And as Dr. Wyngaarden mentioned in his opening statement, for advanced bladder cancer we now have a very effective program that produces complete remissions in roughly 40 percent of the patients. This is quite unique. There is also a new positive study in malignant melanoma.

Since I testified before the House Appropriations Committee, five studies, three in Europe and two in this country, have turned positive for patients with stage one breast cancer.

The Institute is in the process right now of putting together a public service announcement so that the 50,000 women out there who might be eligible for these therapies will be able to know about them before we go through the whole process of publishing and making the data available to doctors. So we have had a lot of progress in those areas.

The biologics program, which was started by moneys provided by the Congress in 1979, has also begun to bloom. We have interferon. We have interluken II, and those studies are going very well.

But this year several clinical studies have been reported positive, using what we call the colony stimulating factors. These are factors that you and I make in our bone marrow so we can produce white blood cells and platelets and red blood cells.

Years ago, we knew these factors were there, but could not use them because we could not make them in quantity. But with genetic engineering, we are now making them by the bucketful, and they have been used in clinical trials, with chemotherapy.

They have been shown to prevent the blood count depression seen and the mouth sores that you get with chemotherapy. So it will allow us to dose patients more adequately. This is probably one of the most exciting advances in cancer treatment research in a very long period of time.

Dr. Fauci will cover, I am sure, all the AIDS work that we share with the NIAID. Let me just conclude with what I think is a major paradox in the cancer situation, to emphasize how important it is for us to keep our eye on the ball in cancer research.

In 1984, after we built a network of programs to apply the results of basic research, we made some projections that using everything we had at hand widely throughout the country we could reduce mortality from cancer by 50 percent.

Cancer is now the No. 2 killer in the country, killing roughly one patient every minute of every day. Even if we hit our goals in the year 2000, cancer will move from the No. 2 killer to the No. 1 killer.

This is because of the aging of the population and because of the decline in mortality from cardiovascular diseases, and because, unfortunately, AIDS is also influencing the incidence of certain kinds of cancers and may drive the incidence up a bit.

So even if we hit what are viewed generally as rather ambitious goals, we have to face the fact that we will be dealing with the No. 1 killer by the year 2000. And we are preparing to do that.

Our budget for 1989, Mr. Chairman, is $1,468,256,000, a 6.4-percent increase over 1988. That does not include the AIDS allocation, which as you know is in the budget of the Assistant Secretary's office. Our share of that is $125 million.

PREPARED STATEMENTS

I would be pleased to respond to questions. Thank you.

[The statements follow:]

# STATEMENT OF DR. CLAUDE LENFANT

I am pleased to address this committee once again on behalf of the National Heart, Lung, and Blood Institute (NHLBI). This year the NIH Centennial and the 40th Anniversary of the NHLBI provided many opportunities to recognize the outstanding research achievements in heart, blood vessel, lung, and blood diseases and blood resources. They also inspired us to look ahead to the impact of these advances on clinical practice, the health of the public, and plans for new research to ensure further significant progress.

The past year has been especially noteworthy for several important research advances that contributed to public health by influencing the attitudes and behavior of health professionals and the general public. I want to report on a few of these advances and tell you about some of our new programs.

A recent (November 1987) announcement that a bioengineered or recombinant form of the naturally occurring tissue plasminogen activator (rt-PA) has been licensed for the early treatment of heart attack victims is an example of a dividend that accrued from an ongoing clinical trial. This rt-PA is a more advanced version of one of the two clot-dissolving or "thrombolytic" agents that we used in an NHLBI clinical trial initiated in 1983. The trial demonstrated the effectiveness of intravenously administered thrombolytic agents for dissolving clots in a blocked artery when used in the early hours after a myocardial infarction. A second stage of the trial has examined whether it is necessary to use percutaneous transluminal coronary angioplasty (PTCA)--commonly referred to as balloon dilatation--immediately after the clot dissolved, or whether use of PTCA, when needed, could be postponed. The general applicability and cost effectiveness of rt-PA therapy would be diminished if immediate PTCA were required because it would necessitate emergency cardiac catheterization, which is not possible in many hospitals and adds hazard and cost. It is therefore gratifying to report that the clinical trial has shown it is safe to postpone angioplasty for at least 18 to 48 hours after thrombolytic therapy with rt-PA. This information will eliminate the need to establish expensive new catheterization laboratories in emergency rooms and the exposure of many patients to unnecessary acute angioplasty.

Chronic obstructive pulmonary disease affects 12 to 14 million Americans and is the fifth leading cause of death in this country. Emphysema, which is an incurable debilitating form of this disease, affects about 2 million people. Of these, about 20,000 to 40,000 have an inherited deficiency of a blood protein, alpha-1-antitrypsin (AAT), which in normal individuals protects the lung from destructive processes that result in emphysema. A recent research advance in our intramural laboratories now provides hope for those who have a genetic deficiency of AAT. It has been shown that weekly infusions of AAT can maintain adequate levels in the lungs and blood of these patients. Now underway are studies to determine if correction of the biochemical abnormality leads to functional benefits for these patients and whether the progression of their emphysema is slowed. A significant aspect of these studies is that the product used is the only one now available that may stabilize this destructive pulmonary disease process, and it now has been approved in this country for use in individuals with a documented genetic deficiency of AAT.

As a result of recent progress in establishing the structure and in cloning the gene of erythropoietin, a hormone that regulates red blood cell production, large quantities of pure recombinant erythropoietin are now available. This development should have a significant impact on treatment of the anemia associated with end stage renal disease, which affects about 85,000 patients in this country. Patients with chronic renal insufficiency require a total of about 300,000 units of red blood cells each year. Because recombinant erythropoietin apparently corrects the anemia, its use should help conserve the national blood supply by reducing the need for red blood cell transfusion in these patients. Recombinant erythropoietin also holds promise for patients with sickle cell disease in whom it stimulates the production of fetal hemoglobin and thus favorably influences the clinical course. Similar benefits may accrue to patients with Cooley's anemia. These new measures not only improve the quality of life of such patients but also provide important economic benefits.

The programs above exemplify how basic research leads to better clinical practice and to considerably improved public health. Thus, the Institute fosters many activities utilizing new approaches such as molecular biology to address clinical problems. A recent instance is the gratifying progress toward elucidating the genetics of cystic fibrosis. The basic defect in this devastating disease of childhood appears to be a breakdown in the regulation of sodium and chloride ion transport across epithelial cell membranes. However, efforts to relate these changes to the genetic abnormality have been hampered by a lack of supply of tissues and cells manifesting the cystic fibrosis defect. Therefore, the Institute is encouraging a basic research program to develop "immortalized" airway epithelial cells from cystic fibrosis patients so that cells expressing the characteristic defect of this disease are available in the laboratory for studies of the basic mechanisms underlying this disease process.

In addition, the Institute's new program in molecular biology will enhance the basic aspects of cardiovascular, pulmonary, and blood-related studies by encouraging innovative development of relevant disciplines and technologies and the training of young investigators.

While we are pleased to report progress, we remain confronted by problems that require our continued efforts. A clinical condition known as silent ischemia is another problem which has raised questions that are sending investigators back to the basic science laboratory for answers. It is now known that patients with coronary artery disease and, to some extent, asymptomatic individuals, experience ischemia without the characteristic anginal pain. The prevalence of silent ischemia, manifested by an abnormal exercise tolerance test in a general but healthy population, has been reported to vary from 2.5 to 10 percent. Annually, of the approximately one-half million individuals who survive a myocardial infarction, about 50,000 will experience painless ischemia on an exercise test prior to hospital discharge, and this portends an adverse prognosis. Research has demonstrated that silent and symptomatic ischemia, which often occur in the same individual, may have different characteristics, patterns, and severity. Further studies of fundamental mechanisms are expected to contribute to our understanding of this problem, to improve our ability to identify individuals at risk for a future cardiac event, and to provide information important for treatment and prevention.

Despite dramatic improvements in control of hypertension and decline of 58 percent in the death rate from strokes in this country, a need remains to better characterize hypertensive patients as a basis for selecting appropriate drug or non-drug interventions. An example of this need is a group of sodium-sensitive hypertensives, whose blood pressure rises in response to excess dietary sodium. Approximately one-half of hypertensives have this sodium-sensitive variety. In recent trials of calcium supplementation, approximately one-half of hypertensive patients responded with a reduction in blood pressure, and the data suggest that sodium-sensitive hypertensives and those who respond to calcium supplementation may very well be one and the same. Furthermore, initial data indicate that when these patients are given additional sodium in their diets, their extracellular calcium falls and their blood pressure rises. However, if they are first given calcium, administering sodium tends not to affect their calcium levels and the rise in blood pressure is prevented. This challenging research is being pursued vigorously. It is of particular interest in relation to black hypertensives because over half are sodium-sensitive. In this context, it is noteworthy that the National High Blood Pressure Education Program is examining factors that may account for the higher death rates from stroke in the southeastern United States, a problem of such magnitude that the region is referred to as the "stroke belt."

That sleep disturbances are a clinical problem caused by more than simply emotional or situational disturbances is now recognized by physicians as well as patients. Cardiopulmonary disorders during sleep, and particularly sleep apnea syndrome, are among the more common of these disturbances. It is now known that this syndrome is not at all rare in the general population and that its incidence is considerably higher among those who are obese or hypertensive. Because the syndrome results in excessive daytime sleepiness and diminished quality of life, it warrants attention and requires the expertise of both basic scientists and clinicians. The Institute is encouraging the development of centers to address such topics as neural control of respiration during sleep, the neurochemical modulation of cardio-respiratory rhythms, the control of cardiovascular function during sleep, and the epidemiology of sleep apnea.

Much of current research on blood diseases and resources is based on the need to correct defects involved in genetic diseases of the blood, to understand and control the process of blood coagulation, and to ensure the purity of blood used in blood transfusion. The Comprehensive Sickle Cell Centers, an important part of the Institute's program, focus on the prevention or correction of complications of this genetic disease, and they have made significant contributions to scientific studies, clinical practice, and patient and public educational activities. This centers program recently underwent competitive renewal, and basic research efforts in the new generation of sickle cell centers offer promising opportunities to advance our understanding of the disease at cellular and molecular levels, to lead to better treatment and prevention approaches, and hopefully to bring us closer to a cure for this disease.

The Institute has long sponsored a comprehensive and coordinated program of research related to blood resources. During the past year, it added the National Blood Resource Education Program to the already successful national education programs to control high blood pressure and high blood cholesterol levels. Building on tested methods of the other programs, the National Blood Resource Education Program is developing educational approaches aimed at potential donors and recipients of blood components, as well as the health professionals who use and manage the nation's blood resource. Scientific advances through our research programs will serve as the basis for the activities of this new effort and, in turn, our research programs will respond to needs identified by the education program.

I am confident that what I have summarized here, as well as our other programs in basic research, clinical research, and clinical trials that are essential to our understanding of the causes of cardiovascular, pulmonary, and blood diseases and resources, will provide the basis for future advances in the treatment and prevention of these diseases.

Mr. Chairman, the FY 1989 budget request for the National Heart, Lung, and Blood Institute is $1,015,471,000. I will be pleased to answer any questions that the committee may have.

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## BIOGRAPHY OF DR. CLAUDE LENFANT

October 12, 1928, Paris, France

Education: B.S., University of Rennes, France, 1948. M.D., University of Paris, France, 1956.

Professional History: 1957-1958, Research Fellow, University of Buffalo, New York. 1958-1959, Research Fellow, Columbia University, New York. 1959-1960, Assistant Professor of Physiology, University of Lille, France. 1961-1965, Clinical Instructor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1966-1967, Clinical Assistant Professor of Medicine and of Physiology and Biophysics, University of Washington, Seattle. 1968-1971, Associate Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1970-1972, Acting Associate Director, Collaborative R&D Program, National Heart and Lung Institute, NIH. 1970-1972, Associate Director for Lung Programs, National Heart and Lung Institute, NIH. 1971-1972, Professor of Medicine and Physiology and Biophysics, University of Washington, Seattle. 1972-1980, Director, Division of Lung Diseases, National Heart, Lung, and Blood Institute, NIH. 1981-1982, Associate Director for International Research, NIH. 1981-1982, Director, Fogarty International Center for Advanced Study in the Health Sciences, NIH. 1982-Present, Director, National Heart, Lung, and Blood Institute, NIH.

Professional Organizations: Association of American Physicians, American Society for Clinical Investigation, American Physiological Society, American Federation for Clinical Research, French Physiological Society, International Federation for Medical Electronics, American Society of Zoologists, Society for Experimental Medicine and Biology, Undersea Medical Society, New York Academy of Science.

Honors, Awards: Thesis Prize, University of Paris, France, 1956. Commendation Tohoku Medical Society, Sendai, Japan, 1973. Superior Service Honor Award, DHHS, 1974. Regents' Professor, University of California, Los Angeles, 1975. Testimonial Dinner, American Thoracic Society, 1979. Honorary Fellow, American College of Chest Physicians, 1979. Honorary Professor, National Yang-Ming Medical College Taipei, Taiwan, 1980. Honorary Professor, Universidad Peruana Cayetano Heredia, Lima, Peru, 1981. Senior Executive Service Performance Award, 1982. Elected Institute of Medicine, National Academy of Sciences, 1983. American Heart Association Scientific Councils' "Distinguished Achievement Award," 1983. Senior Executive Service Performance Award, 1983. Honorary Fellow - Council on Clinical Cardiology - American Heart Association, 1984. Senior Executive Service Performance Award, 1984. Forrest M. Bird Contributory Award, American Respiratory Therapy Foundation, 1985. Senior Executive Service Performance Award, 1985. Presidential Meritorious Executive Rank Award, 1987. Elected Honorary member, Royal Society of Medicine, England, 1988. Honorary Doctor of Science, State University of New York, Buffalo, 1988.

Authorship, Editorship: Author or Co-Author of 192 scientific publications Served on Editorial Boards of: Am. Journal of Physiology; Journal of Applied Physiology; Respiratory Physiology; Am. Review of Respiratory Disease; Undersea Biomedical Research; Proceedings of Society for Experimental Biology and Medicine; Revue Francaise des Maladies Respiratories; Journal of Applied Physiology; Respiration, Environmental and Exercise Physiology;

Am. Journal of Medicine; Continuing Education for Family Physicians; Executive Editor of 38 volume monograph series, Lung Biology in Health and Disease.

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## STATEMENT OF DR. ANTHONY S. FAUCI

We have discussed on several occasions before this Committee the prevailing theme of the National Institute of Allergy and Infectious Diseases (NIAID)--the study of the immune system as an organ system, which when functioning properly protects the body against viruses, bacteria, and other microorganisms as well as against the development of certain cancers. Like any other organ system, the immune system can malfunction, either overfunctioning to produce allergies or hypersensitivity disorders, or functioning too little, resulting in immunodeficiency diseases, the most widely recognized of which is now the acquired immunodeficiency syndrome, or AIDS.

An extraordinary expansion of knowledge of the basic mechanisms of immune system function over the past two to three decades has led to a greater appreciation of its role in protecting the body as well as its dysfunction in certain diseases. This progress is highlighted in 1988 as we observe the fortieth anniversary of NIAID, first established as the National Microbiological Institute when NIH was reorganized in 1948. Forty years ago, our understanding of the immune system was so elementary and basic that the specific functions of cells of the immune system were unknown. Since then, not only have we vastly increased our knowledge of the subtle and intricate relationships between cells, but we have begun to understand at the molecular level the workings of the immune system and the microbes that it protects against. This makes our research extremely exciting and fulfilling, particularly as we are able to manipulate genes, regulate the immune system, manufacture recombinant vaccines, or interfere with or alter the infectivity of microorganisms.

The important role of basic research in medical science and ultimately in the health of our nation is made especially evident with the award of the 1987 Nobel Prize for Physiology or Medicine to an NIAID grantee, Susumu Tonegawa. Dr. Tonegawa was recognized for his brilliant research demonstrating that the limited number of genes that carry the instructions for the manufacture of antibodies are shuffled within developing cells to create literally millions of possible combinations. In this way, the body can produce a seemingly limitless number of antibodies, each specifically targeted at an invading microbe or foreign substance. Thus, the great mystery of how the immune system maintains its scope as well as its specificity has been solved. As the Nobel Committee stated, the knowledge gained from Dr. Tonegawa's experiments has broad applications to medical science, including vaccine development, transplantation biology, asthma, hypersensitivity disease, and autoimmunity. Similar spin-off results might be projected from the hundreds of ongoing basic research projects being conducted by the scientists working in NIAID's laboratories in Bethesda and at our Rocky Mountain Laboratories in Hamilton, Montana, and by the scientists we support at universities, medical centers, and hospitals throughout this country and abroad.

The AIDS epidemic continues to be a major concern. NIAID has taken the lead role in the basic and clinical studies of the acquired immunodeficiency syndrome, an infectious disease of the immune system. A significant advance in our understanding of the disease process in AIDS includes the precise delineation of the nature of the mechanisms whereby the human immunodeficiency virus (HIV) binds to and destroys cells of the immune system. For some time it was known that the T4 lymphocyte, which is the critical inducer cell of the immune system responsible for regulating all the other components of the system, was the major target that is destroyed by HIV. Recently it was discovered that monocyte-macrophages, the scavenger cells of the immune system, can also be infected by the virus but are not destroyed. The monocyte-macrophage thus serves as the major reservoir of the virus and can actually spread the virus to different parts of the body. This finding has presented an additional hurdle in the search for therapeutic agents that can remove the virus from the body.

Increased knowledge of how the virus invades the brain and affects specific cells in the brain is enabling us to understand the precise mechanisms of the neuropsychiatric abnormalities seen in many persons with AIDS. Although the immune system and the brain are the major targets of HIV infection, the clinical manifestations of AIDS are myriad and heterogeneous. An understanding of this heterogeneity is being advanced through our increased knowledge about the cellular receptor for HIV, which is a molecule called CD4, and the recognition that any cell possessing a CD4 molecule is potentially able to bind to and be infected with HIV.

The techniques of molecular virology are proving crucial to our understanding of this complex virus. Having identified all of the genes of HIV, scientists have delineated the functions of essentially all of the viral genes and, through recombinant DNA technology, have been able to produce the gene products in usable form for research purposes. In this regard, NIAID is establishing a reagent repository that will collect and disseminate cloned HIV genes, viruses, antisera, and other research materials. In the spirit of international cooperation, this repository will also serve as one of three designated World Health Organization (WHO) AIDS reagent repositories in the world. An additional international research resource has been established by NIAID at Los Alamos National Laboratory for the collection and dispersal of genetic data pertaining to AIDS. This Genetic Sequence Data Base is vitally important because of the speed with which genetic information about HIV is being reported, the rapid mutations of the virus resulting in different genetic sequences of each viral isolate, and the need for more information on other retroviruses such as HIV-2.

We have used our understanding of the precise functions of the various genes and the proteins they manufacture to set up a targeted approach to antiviral therapy. In this regard, NIAID has established 18 National Cooperative Drug Discovery Groups, each a multidisciplinary team of talented scientists from academia, industry, and government. This consortia has already produced several products that will likely enter clinical testing by next winter.

Important clues to targeted approaches to both antiviral therapy and vaccine development are being provided by structural biology, which is the study of relationships between the molecular structure of a particular organism and its biological functions. By examining the three-dimensional structure of viral proteins through the precise techniques of x-ray crystallography, scientists can identify or design compounds that can interfere with binding of virus to cells or interfere with specific functions of the virus. X-ray crystallography is becoming a major tool of investigators not only in AIDS research but in molecular research in a variety of other areas. Large amounts of purified protein are needed for this important basic research, and we are now in the process of scaling up to furnish these raw materials.

NIAID research on treatment for AIDS includes investigations of drugs that will inhibit viral infectivity and replication, biologic response modifiers that will strengthen the immune response, bone marrow transplants and transfer of lymphocytes to restore immune function, and drugs and other therapies to combat AIDS-related opportunistic infections and cancers.

We are conducting AIDS treatment research both in the intramural program at the NIH Clinical Center and through our nationwide network of clinical investigators. Last fall, we launched an initiative that will greatly expand our capacity to conduct controlled, clinical trials of experimental therapies in a wide variety of patient populations, adding 17 new Clinical Studies Groups to our existing AIDS Treatment Evaluation Units, forming a cohesive network called the AIDS Clinical Trials Group. We regard this AIDS Clinical Trials Group as a national resource for drug development and testing, with a major goal being the timely transfer of information to the thousands of community physicians who must select the most appropriate therapies for their patients with AIDS.

At the present time, there is one licensed drug, azidothymidine (AZT), that has been shown to be effective in prolonging the lives of individuals with AIDS. Although this drug constitutes a major advance in the therapy of HIV infection, it is by no means the solution to the problem since it is not effective in every patient and it has significant toxic side effects, particularly in seriously ill patients. It is for these reasons that we are continuing to develop and evaluate a variety of other drugs with potential for efficacy against HIV. Furthermore, the favorable results with AZT in seriously ill patients serve as the basis for early intervention studies in which AZT at various doses, either alone or in combination with other drugs, is being tested in patients with less serious manifestations of HIV infection. A double blind, placebo-controlled study of AZT in 1,600 asymptomatic HIV-infected persons, now ongoing in our AIDS Clinical Trials Group, has potentially important implications for the ability to block the progression from asymptomatic carrier state to full blown disease in the greater than one million people in this country who are infected with the virus. Hopefully, when we come before this Committee next year we will be able to report the preliminary results of this study.

Vaccine development and evaluation provide one of our greatest challenges in combatting the AIDS epidemic. A major difficulty is the lack of a full understanding of the nature of an effective immune response to HIV infection. Unlike the situation with other infectious diseases such as influenza or polio, no readily apparent correlations exist between immune responses to HIV and recovery from infection. Other difficulties in the development of a protective vaccine are the complexity of the organism, the antigenic variations among isolates, and the paucity of suitable animal models in which to test candidate vaccines. Despite these complications, NIAID is forging ahead in AIDS vaccine development. Possible approaches in developing AIDS vaccine preparations include the use of whole killed HIV, purified natural products of the virus, synthetic peptides (small proteins) of virus subunits, recombinant DNA products, and vaccines produced by insertion of genetic material from HIV into live vaccinia virus. To encourage the pursuit of all scientifically sound approaches to AIDS vaccine development and to attract creative scientists into the field, we have established several National Cooperative Vaccine Discovery Groups, consisting of multi-institutional, multidisciplinary teams of scientists from academia and industry. In addition, NIAID is playing a major role in the broader NIH AIDS vaccine plan, which includes basic research, preclinical development, and clinical testing.

An important first step in vaccine testing was made last October when NIAID began clinical studies of the first AIDS vaccine approved by the Food and Drug Administration for testing in human volunteers. Several of our scientists played major roles in developing the recombinant vaccine, which consists of purified envelope protein derived from the genetic material of HIV. In Phase I trials being conducted at the NIH Clinical Center and at our six Vaccine Evaluation Units located at university medical centers, the vaccine is being evaluated for safety and the ability to evoke an immune response. This is just the first of what we anticipate will be a number of candidate AIDS vaccines that will be considered for testing in the Vaccine Evaluation Units.

Apart from AIDS research, we are pursuing with great interest and accelerated activity our work on delineating the precise mechanisms of allergic responses and developing better diagnostic and therapeutic approaches to benefit patients with allergies. We have intensified our activities in the area of transplantation biology, and, as part of our continued commitment to improved diagnosis and treatment of sexually transmitted diseases, we have established a number of centers for the study of pelvic inflammatory disease, a major cause of infertility in women. We have intensified our activities in the area of transplantation biology.

A classic example of major progress over the past several years is the story of research on vaccines, which protect against the wide range of infectious organisms that besiege the human species. It is of interest that scientists were able to develop highly effective vaccines against certain diseases, such as polio, with very little basic knowledge of the regulatory mechanisms of the immune system. Now that we stand on much firmer scientific ground, and are able to incorporate molecular biology and recombinant DNA technology into our efforts, we have greatly accelerated our ability to provide new and improved vaccines against a number of diseases. Improved vaccines such as a recently licensed hepatitis B vaccine and experimental vaccines against pertussis, or whooping cough, reflect the incorporation of molecular biology into our research armamentarium. Almost certainly, use of recombinant DNA technology will have a major impact on our ability to develop vaccines against common diseases of the developing world such as malaria and leprosy.

This committee has taken a keen interest in NIAID's efforts to develop and test new, improved vaccines for pertussis. The present vaccine, although highly effective in preventing disease, occasionally produces adverse side effects that in rare instances lead to permanent brain damage or death. Just a few weeks ago, we announced the first results of a large study, conducted in Sweden, comparing two Japanese acellular pertussis vaccines. Both vaccines gave significant protection against whooping cough, with many fewer instances of side effects than have been reported from use of the present vaccine. These and other promising pertussis vaccines will continue to be evaluated in NIAID's Vaccine Evaluation Units as part of our vigorous pursuit of an improved pertussis vaccine for use in the United States within the next few years.

In addition to pertussis, the NIAID vaccine program is giving high priority to research on new or improved vaccines for a number of other agents, and is studying more than 190 antigen preparations for 36 different organisms. For example, NIAID scientists have contributed greatly to the development of vaccines against rotaviruses, the most important cause of infant diarrhea. Diarrheal diseases are responsible for over a million deaths per year among young children in the developing world and are an important cause of illness among infants and young children in developed nations as well. Recent successful tests of a combination human-rhesus rotavirus vaccine by NIAID scientists make the prospects for development of a rotavirus vaccine excellent.

The need for rapidly obtainable, clinically applicable results of medical research is urgent. At the same time, we have seen that the quickest and most effective path to this end is to support scientists in the exercising of their intellect, curiosity, and imagination. Thus, our most important goal continues to be the commitment to and encouragement of basic research in immunology, allergy, and infectious diseases, supporting the pursuit of science along the paths where basic research leads.

Mr. Chairman, the 1989 budget request for this Institute is $435,084,000. will be pleased to answer any questions you may have.

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## BIOGRAPHY OF DR. ANTHONY S. FAUCI

December 24, 1940. Brooklyn, New York

Education:

College of Holy Cross, 1962 - A.B.; Cornell University Medical College, 1966 - M.D.

Professional History:

1966-1967, Intern, Department of Medicine, New York Hospital-Cornell Medical Center. 1967-1968, Assistant Resident, Department of Medicine, The New York Hospital-Cornell Medical Center. 1968-1970, Clinical Associate, Laboratory of Clinical Investigation, National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Bethesda, Maryland. 1970-1971, Senior Staff Fellow, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1971-1972, Chief Resident, Department of Medicine, New York Hospital-Cornell Medical Center; Instructor in Medicine, Cornell Medical College. 1972-1974, Senior Investigator, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1972-present, Consultant in Infectious Diseases, The National Naval Medical Center, Bethesda, Maryland. 1974-1980, Head, Clinical Physiology Section, Laboratory of Clinical Investigation, NIAID, NIH, Bethesda, Maryland. 1977-1984, Deputy Clinical Director, NIAID, NIH, Bethesda, Maryland. 1980-present, Chief, Laboratory of Immunoregulation, NIAID, NIH, Bethesda, Maryland. 1984-present, Clinical Professor, Department of Medicine, Division of Rheumatology, Immunology, and Allergy, Georgetown University School of Medicine, Washington, D.C. 1985-present, Clinical Professor, George Washington University School of Medicine and Health Sciences, Washington, D.C. 1984-present, Director, NIAID, NIH, Bethesda, Maryland.

Board Certification and Military Service:

American Board of Internal Medicine-June 21, 1972. American Board of Allergy and Immunology-March 1, 1974. American Board of Infectious Diseases-October 15, 1974. U.S. Public Health Service, July 1968-June 1970; July 1972-Present.

Professional Organizations:

American Federation for Clinical Research, American Association for the Advancement of Science, American Association of Immunologists, American Medical Association, Fellow of the American Academy of Allergy, Infectious Diseases Society of America, American Society for Clinical Investigation, Fellow of The American College of Physicians, Association of American Physicians, Collegium Internationale Allergologicum, Charter Member of the Clinical Immunology Society. The Institute of Medicine of the National Academy of Sciences (USA).

Offices Held:

Councillor, Eastern Section, American Federation for Clinical Research (AFCR), 1977. National Councillor, AFCR, 1978-1979. President, AFCR, 1980-1981.

Advisory Boards and Committees:

Chairman, Allergy and Immunology Committee, MKSAP V, American College of Physicians. Advisory Panel, The American Board of Medical Laboratory Immunology. Member, Committee on Clinical Immunology and Immunopathology, American Association of Immunologists, 1980-1985. Representative of American Association of Immunologists to the Examinations Committee of the American Board of Allergy and Immunology, 1981-present. Postgraduate Education Committee, American Academy of Allergy, 1979-1982. Member, NIAID Study Group on Immunology, 1980. Member, Section of Physiology in Clinical Science of the American Physiological Society, 1980-1984. Member, Subcommittee on the Classification of Vasculitis, American Rheumatism Association 1980-present. Ad Hoc Committee, The National Foundation for Infectious Diseases, 1980-present. Subcommittee on Clinical Sciences, Publications Committee, American Physiological Society, 1980-1984. American Association of Immunologists, 1982-1985. Member, NIAID Working Group for AIDS, 1982-present. Member, American Federation for Clinical Research President's Public Policy Advisory Committee, 1983-present. Board of Directors, American Board of Allergy and Immunology, 1984-1987. Participant in the USA - People's Republic of China Immunology Cooperative Agreement, August 10-22, 1983, Beijing and Shanghai, PRC. Member, Scientific Advisory Board, Medical Biology Institute, La Jolla, CA, 1983-1984. Participant in the USA-Japan Eye Immunology Advisory Conference, November 27 to December 1, 1983, Honolulu, HI. Member, External Advisory Committee, Multipurpose Arthritis Center, Duke University Medical Center, 1984-present. Member, Honorary Advisory Board, Italian-American Medical Association, 1984-present. Member, Peripatetic Club, 1984-present. Ex Officio Member, National Diabetes Advisory Board, 1984-present. Ex Officio Member, National Digestive Diseases Advisory Board, 1984-present. Chairman, Search Committee for Director, National Institute of Child Health and Human Development, 1985. Member, Department of Health and Human Services Task Force on Alzheimer's Diseases. The Albert Lasker Medical Research Award Jury, 1985-present. Deputy Ethics Counselor, Department of Health and Human Services, 1985-present. Member, Department of Health and Humans Services Committee to Coordinate Environmental and Related Programs, 1985-present. Member, Scientific Organizing Committee, Joint Meeting of the Italian Society of Immunology and Immunopathology-National Institutes of Health on "Human Lymphocyte Activation," Florence, Italy, September 5-7, 1985. Member, United States Delegation to the United States-Japan Cooperative Medical Science Committee, 1985-present. Member, U.S. Public Health Service AIDS Executive Task Force, 1985-present. Chairman, NIH AIDS Executive Task Force, 1985-present. Coordinator, NIH AIDS Research, 1985-present. Member, Scientific Seminar Subcommittee, National Institutes of Health Centennial Program, 1985-1987. Member, Advisory Board, Clinical Immunology Newsletter, 1986-1988. Member, Scientific Organizing Committee, International Conference on Lymphocyte Activation and Immune Regulation, Newport Beach, CA, February 28-March 2, 1986. Member, Planning Committee, Clinical Immunology Society, 1986. Member, International Advisory Committee, International Conference on AIDS, Paris, France, June 23-25, 1986. Member, Advisory Group, Institut Scientifique Roussel-Uclaf, 1987-1989. Ex Officio Member, National Kidney and Urologic Diseases Advisory Board, 1987-present. Member, International Programme Committee, 8th International Congress of Immunology, Budapest, Hungary, 1987. Member, International Advisory Committee, IVth International Conference on AIDS, Stockholm, Sweden, June 12-16, 1988. Member, NIH Resource Allocation Group, 1987-1989.

Editorial Boards:

Dr. Fauci has been or is on the Editorial Board of 27 scientific journals in the field of immunology, allergy and infectious diseases. These include: The Journal of Clinical Investigation, The Journal of Immunology, Journal of Infectious Diseases, Journal of Clinical Immunology. Dr. Fauci is also the Editor of one of the major textbooks of medicine in the world, "Harrison's Principles of Internal Medicine."

Awards and Honors:

Alpha Omega Alpha. Kileen Prize for Excellence in Chemistry (College of the Holy Cross). John Metcalfe Polk Prize for General Efficiency (Cornell University Medical College). Alfred Mortitz Michaelis Prize for Efficiency in General Medicine (Cornell University Medical College). U.S. Public Health Service Meritorious Service Award, 1979. Arthur S. Flemming Award, 1979 - Given to the 10 outstanding employees in the U.S. Federal Government. Squibb Award of the Infectious Diseases Society of America, 1983. U.S. Public Health Service Distinguished Service Medal, 1984. Food and Drug Administration Commissioner's Special Citation, 1984. 1985 Citation Classics (Current Contents) for article - A.S. Fauci, D.C. Dale, and J.E. Balow: Glucocorticosteroid therapy: mechanisms of action and clinical considerations. Ann. Intern. Med. 84: 304-315, 1976. Who's Who in America, 44th Edition. Who's Who in Science and Technology, 2nd Edition. 1985 Stanford University Center Survey of the American Rheumatism Association membership ranked the work of Dr. Anthony S. Fauci on the treatment of polyarteritis nodosa and Wegener's granulomatosis as one of the most important advances in patient management in rheumatology over the past 20 years. The Clemens von Pirquet Award of Georgetown University Medical Center, 1986. Doctor of Science, Honoris Causa, College of the Holy Cross, Worcester, MA May 29, 1987. Professor of Medicine at a large number of major medical schools throughout the country.

Publications:

Dr. Fauci has authored over 600 scientific publications in the field of basic and clinical immunology and infectious diseases.

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## STATEMENT OF DR. HARALD LÖE

Mr. Chairman, on June 24, 1988, the National Institute of Dental Research (NIDR) will celebrate its 40th anniversary. We view this as a time for looking back at what we have achieved in four decades of oral health research and looking ahead to where we see research going. I think it is no exaggeration to say that 40 years of federally supported dental research have changed the face of America--for the better!

Consider how the nation looked 40 years ago. America had barely emerged from World War II--a war in which dental defects were the leading physical reason for rejection of recruits. Nearly 10 percent of the young men drafted into the Army failed to meet the minimum requirement of having six opposing teeth in each jaw. Indeed, the standard had to be relaxed and dentures supplied to servicemen in order to enlist enough troops to fight the war.

Those alarming facts were not lost on the Government--nor was the lesson forgotten that Government-sponsored research could--and did--turn the tide of war. With the momentum of victory and the machinery for research in place, the Federal government began to build a peacetime research enterprise that was unrivaled in the world. For the National Institutes of Health it was an era of rapid growth, with the addition of new institutes focused on pressing health problems. The need to combat dental diseases--endemic, chronic, painful and costly--united the dental community and Congress in efforts that led to the creation of NIDR as the third of the National Institutes of Health.

Almost immediately the pace of progress in dental research accelerated, with discoveries that would revolutionize dentistry worldwide. The first revolution came with the evidence that fluoride could protect teeth against decay (dental caries). In the 1930s and 1940s a few dental investigators, collecting data on tooth decay, observed that people who had lived all their lives in communities where the drinking water was naturally rich in fluoride had the lowest levels of decay. Optimal levels for fluoride in drinking water were soon established and led to one of the most successful preventive health projects in history. On January 25, 1945, the town of Grand Rapids, Michigan, became the first city in the world to fluoridate its drinking water.

Today 300 million people in the world are served by fluoridated drinking water. Over 90 percent of toothpastes sold in the United States contain fluoride and there are other over-the-counter fluoride products as well. In addition, prescription fluoride tablets and professional fluoride applications are available for people who lack access to fluoridated water or who are highly susceptible to decay. Now we are seeing the growing adoption of dental sealants, thin plastic films that dentists can apply to the chewing surfaces of children's teeth to prevent decay in areas hard to reach by fluoride.

In a survey completed in 1980 the NIDR showed that over a third of school children ages 5-17 are now completely caries-free, while the prevalence of decay in the remaining children was only half what it was a generation ago. Dental research has already changed the face of America's children.

We estimate that the decline in caries translates into savings of more than $2 billion a year in the nation's dental bill. That sum is more than the total appropriations NIDR has received in its entire 40-year history.

Soon we will be reporting on a repeat children's survey, one in which we expect to see that the declines in caries are being sustained and perhaps extended, so that an even greater proportion of children may be caries free.

Still, the battle is not over. Some children are very vulnerable to decay. Some children will develop caries as they grow older, as do adults and even our oldest citizens--facts we learned in the survey of adult oral health we reported on last year. Our 1985-86 National Survey of Employed Adults and Seniors marked another major event in the history of the NIDR. For the first time in 40 years we had up-to-date statistics on a sample of the U.S. population representing over 100 million Americans. For the majority of these people the news was gratifying: Working adults are enjoying a degree of oral health that may be unsurpassed in the world. A most remarkable finding was that only 4 percent of employed adults between ages 18 and 65 were missing all their teeth--truly an impressive change in the face of middle-aged America.

But older Americans are not faring as well. We found that 42 percent of adults 65 and over were toothless. Those with teeth continue to suffer decay on both the crowns and roots of teeth and they have more severe and extensive periodontal disease problems.

We have pledged to expand research on their behalf, building on all that we have learned since the second great advance in dentistry which occurred in the 1950s and 1960s: the demonstration that dental caries and the periodontal diseases are both bacterial infections associated with microorganisms in plaque, the film of bacteria that builds up on teeth and gums.

Those discoveries opened up whole new lines of research. By the mid-1960s the NIDR also had set in place a new mechanism--the Dental Research Institute and Centers program--to act as a magnet attracting scientists from other fields to dental research. The magnetism worked and started a process of cross-fertilization and growth of dental research that has never stopped.

Out of the microbiology studies came the identification of specific strains of Streptococcus mutans as the principal bacteria involved in dental caries, and several species of bacteria associated with periodontal diseases. These and other critical experiments are revealing how these microorganisms colonize oral tissues and attack the host.

In parallel with the findings of the microbiologists have come revelations from immunologists studying how the body's defense mechanisms respond to disease. Today, we owe an ever-deepening understanding of these mechanisms to the advent of cell and molecular biology. We can now map the traffic in and out of cells and catalogue the major and minor molecules directing that traffic and ultimately determining the fate of cells. We know now that some bacteria extend fine filaments to attach to other bacteria or to oral tissues; we know that certain bacteria can generate toxins that destroy tissues directly or factors that subvert the body's defense mechanisms. We have learned that bacteria themselves engage in combat, sometimes forming peaceful coalitions, at other times unleashing chemical weapons to destroy their competitors.

This new information is being applied to novel approaches to the treatment and prevention of disease. We can manipulate bacteria to disarm their destructive weapons; we can deprive them of their metabolic necessities; we can raise new harmless strains that can compete and replace the oral pathogens, and we can undo the harm they initiate in the body's tissues by enhancing repair and regeneration. An example of the fruits of these approaches is a new drug called chemically modified tetracycline (CMT). This is tetracycline without its antibiotic property, but with the property of inhibiting the body's production of pathologically high levels of an enzyme that destroys collagen. It is collagen destruction that leads to the wasting away of the supporting tissues of the teeth in periodontal diseases--and also to the painful wasting and inflamed joints seen in rheumatoid arthritis and other connective tissue disorders. The advantage of CMT is that it can be used for long periods of time without danger of inducing bacterial resistance.

This is one example of the clinical insights gained from dental research that are having far-reaching implications for chronic degenerative diseases affecting other organs of the body. The example also explains why, over the course of 40 years, the Dental Institute has maintained leadership in the study of connective tissue and bone, the tissues that form the supporting fabric of the body's organs and provide the strong structural framework.

Basement membranes form part of this connective tissue fabric. These membranes are thin sheaths of extracellular material that underlie skin and surround nerves, blood vessels and other organs. Studies of basement membrane have led to a major finding about cancer. Dental investigators have shown that when cancer cells invade other tissues (the process of metastasis), it is because a small population of malignant cells is able to migrate to the basement membrane, bind to a major protein component of the membrane called laminin, degrade the membrane, break through and invade other tissues. Not only did dental researchers discover laminin, but they also have determined its chemical structure and used this information to synthesize drugs which prevent cancer cells from binding and thus invading other tissues.

This focus on the structure and function of molecules found in and outside cells is at the forefront of biomedical research today. It is the story of growth factors, hormones, neurotransmitters, enhancers, silencers, and other molecules that bind to DNA to regulate the growth and development of an organism. Future research in this area can be expected to reveal how cells and tissue form and how a single fertilized egg cell grows and differentiates into a mature organism.

The role and function of saliva can serve as another example of the importance of these extracellular components. We now know, thanks to dental research over the last decade, that the primary role of the saliva is to protect and maintain the health of the oral tissues. Saliva contains its own broad spectrum antibacterials and antifungals: lysozyme, lactoferrin, histidine-rich proteins, to name a few. Salivary glands also secrete antibodies targeted to specific bacteria or viruses. Saliva is rich in calcium and phosphates that are used to repair incipient cavities caused by decay-causing bacteria. With the use of genetic probes and monoclonal antibodies we can test saliva samples for antibodies to disease, for the presence of specific viruses, bacteria, or other pathogens. Saliva can also be used to monitor levels of drugs or the body's own tissue products as signs of disease.

We are seeing this knowledge pay off today in studies of AIDS in which dental scientists are documenting changes in salivary chemicals which may occur very early in infection. These same investigators are studying whether

AIDS can be spread through saliva. The evidence, so far, would indicate that there is very little likelihood of transmission by this route.

Microbiology, immunology, salivary gland studies...only begin to tap the vast field that dental science has become in 40 years. We began with a mission to combat the burden of dental diseases, the tooth decay and gum diseases that led to a mouthful of gold and silver restorations or else to the full dentures that were an accepted fact of life after 40. Research disclosed what caused these diseases and pointed the way to prevention. We started the prevention process with children and we are continuing to reduce the risk of disease and lower the numbers affected by focusing on those children who are at high risk, using new diagnostic tools that can lead to early interventions to prevent or reverse the disease process.

Our adult survey has taught us that we still have a way to go. We need to sharpen our diagnostic tools, especially in the case of periodontal diseases. We need to develop better preventive measures, such as new and targeted antibacterials to make it easier for adults to maintain oral health. At the basic research level, we need to understand how the oral environment changes with aging and what we can do to enhance immune defenses, repair, and regeneration. This attention to adult oral health problems means that we must expand our competence in diagnosing, treating, and preventing oral cancers and other soft tissue diseases. We must take into account systemic conditions like diabetes and autoimmune disorders that have severe oral complications. And then we have to translate those findings rapidly for the benefit of the public and the practitioner through expanded activities in oral disease prevention research and science transfer activities. We have begun this effort already by calling on experts in the development of a comprehensive plan for the control of oral disease. This activity will ultimately involve concerned health care agencies, industry, the profession, and the public.

I am also pleased to report that we have had an extraordinary response to a Request for Applications for Research Centers on Oral Health in Aging which we issued last fall. We hope, as well, to expand the interdisciplinary center approach to other areas relevant to adult oral health--materials science, chronic pain, the molecular biology of growth and repair. These initiatives will be spelled out in more detail as we develop a new research plan for the nineties. Now in its formative stages, the plan will be the blueprint that will take us to the year 2000--and ensure an even greater impact on the face of America.

Mr. Chairman, the FY 1989 budget request for the National Institute of Dental Research is $127,157,000. I will be pleased to answer any questions.

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## BIOGRAPHY OF DR. HARALD LÖE

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| PRESENT POSITION: | Director, National Institute of Dental Research<br>National Institutes of Health<br>Bethesda, Maryland 20892 |
| BIRTHPLACE AND DATE: | July 19, 1926, Steinkjer, Norway |
| CITIZENSHIP: | United States of America |
| DEGREES: 1952 | D.D.S., Oslo University, Norway |
| 1961 | Dr. Odont., Oslo University, Norway |
| 1973 | Honorary Doctorate, University of Gothenburg, Sweden |
| 1980 | Honorary Doctorate, Royal Dental College, Aarhus, Denmark |
| 1980 | Honorary Doctorate, University of Athens, Greece |
| 1980 | Honorary Doctorate, Catholic University of Leuven, Belgium |
| 1983 | Honorary Doctorate, University of Lund, Malmo, Sweden |
| 1983 | Honorary Doctorate, Georgetown University School of Dentistry, Washington, D.C. |
| 1985 | Honorary Doctorate, University of Bergen, Norway |
| 1986 | Honorary Doctorate, University of Maryland |
| 1987 | Honorary Doctorate, University of Medicine & Dentistry of New Jersey |
| 1987 | Honorary Professorship, Medical Sciences University of Beijing, China |

PAST POSITIONS:

| | |
|---|---|
| 1974-1982 | Dean and Professor of Periodontology University of Connecticut School of Dental Medicine, Farmington, Connecticut |
| 1972-1974 | Professor of Dentistry and Director Dental Research Institute, University of Michigan, Ann Arbor |
| 1971-1972 | Associate Dean and Dean-elect Royal Dental College, Aarhus, Denmark |
| 1966-1967 | Visiting Professor of Periodontics Hebrew University, Jerusalem, Israel |
| 1962-1972 | Professor of Dentistry and Chairman Department of Periodontology, Royal Dental College, Aarhus, Denmark |
| 1960-1962 | Associate Professor, Department of Periodontology School of Dentistry, Oslo University, Norway |
| 1959-1962 | University Research Fellow, Oslo University, Norway |
| 1957-1958 | Fulbright Research Fellow and Research Associate, Department of Oral Pathology, University of Illinois, Chicago, Illinois |
| 1956-1962 | Research Associate, Norwegian Institute for Dental Research, Oslo, Norway |
| 1952-1955 | Instructor in Operative Dentistry, School of Dentistry, Oslo University, Norway |

## PROFESSIONAL ACTIVITIES:

| Governmental | |
|---|---|
| 1988 | Member, Central Services Review Committee, NIH |
| 1987 - | Consultant, Medical Research Council (UK) |
| 1987 | Consultant, Medical Research Council (Norway) |
| 1985 | Consultant, The Lord Robens Appeal, British Society for Dental Research (UK) |
| 1985 | Consultant, Ontario Council on Graduate Studies (Canada) |
| 1985-1988 | Consultant, U.S. Naval Medical Command |
| 1984-1986 | Member, Evaluation Policy & Oversight Committee, NIH |
| 1983- | Ex Officio Member, National Diabetes Advisory Board |
| 1979- | Member, Oral Research Advisory Group, WHO |
| 1975-1976 | Member, Scientific Panel to Evaluate the NIDR Periodontal Disease Research Activity, NIH |
| 1974-1977 | Member and Chairman, Dental Drug Products Advisory Committee, U.S. Food and Drug Administration |
| 1971-1972 | Member, Medical Research Council (Denmark) |
| 1969 | Consultant to the Director, NIDR, NIH |
| 1969-1972 | Member, Committee on Dentistry, Danish Foreign Ministry Technical Aid to Developing Countries |

| Corporate | |
|---|---|
| 1980-1981 | Member, Professional Advisory Panel on Preventive Dentistry, Johnson & Johnson, New Brunswick |
| 1969-1976 | Consultant, Procter & Gamble Company, Cincinnati |

| Editorial | |
|---|---|
| 1988 | Reviewer, Editorial Board of Review, Journal of the American College of Dentists |
| 1986-1988 | Reviewer, New England Journal of Medicine |
| 1986 | Supporting Editor, Current Titles in Dentistry |
| 1984-1988 | Member, Editorial Board, Geriodontics |
| 1984-1988 | Member, Journal Committee, American Academy of Periodontology |
| 1983-1987 | Member, Advisory Board, Journal of Clinical Periodontology |
| 1979-1988 | Member, Editorial Board, Clinical Preventive Dentistry |
| 1979-1982 | Consultant, Journal of the American Dental Association |
| 1974-1982 | Foreign Expert Member, Journal of the Indian Dental Association |
| 1973-1977 | Member, Editorial Board, Acta Odontologica Scandinavica |
| 1973-1975 | Member, Editorial Board, Journal of Community Dentistry & Oral Epidemiology, Munksgaard, Copenhagen |
| 1973 | Member, Editorial Board, Journal of Preventive Dentistry, Masson Publishing USA, Inc., New York |
| 1965-1985 | Founding Editor, Journal of Periodontal Research, Munksgaard, Copenhagen, Denmark |
| 1965-1972 | Board of Directors, Acta Odontologica Scandinavica, Munksgaard, Copenhagen, Denmark |
| 1962 | Associate Editor, Scandinavian Journal of Dental Research, Munksgaard, Copenhagen, Denmark |

| Organizational | |
|---|---|
| 1988 | Member, Search Committee for Editor of Journal of Periodontology, American Academy of Periodontology (AAP) |
| 1985-1988 | Member, Subcommittee on Information Related to Periodontal Therapy, AAP |
| 1985-1987 | Chairman, American Association for the Advancement of Science, Section on Dentistry (R) |
| 1983- | Member, Commission on Oral Health Research and Epidemiology, Federation Dentaire Internationale |

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|---|---|
| 1983- | Consultant, Council on International Relations, American Dental Association (ADA) |
| 1979-1981 | President, International Association for Dental Research (IADR) |
| 1977-1982 | Consultant, Council on Dental Therapeutics, ADA |
| 1976 | Member, Committee on Outreach Activities, University of Connecticut, Farmington |
| 1974-1975 | Member, Research Policies Committee, University of Michigan Senate, Ann Arbor |
| 1973-1975 | Member, Review Panel, Grants & Allocations Advisory Committee, American Fund for Dental Education |
| 1972 | Founding Member of the Scandinavian Society of Periodontology |
| 1970-1971 | President of the IADR Periodontal Research Group |
| 1969-1974 | Chairman and Member, IADR Basic Research in Periodontal Disease Award Committee |
| 1968-1970 | Member, Board of Trustees, Danish Dental Association |
| 1966 | Secretary, Pathology Section at the World Workshop in Periodontics, Ann Arbor |
| 1959-1961 | Chairman and Member of the Committee on Post-graduate Education, Oslo Dental Society, Norway |
| 1953-1957 | Member, various administrative committees, Norwegian Dental Association |

Other

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|---|---|
| 1959-1961 | Private practice in periodontics |
| 1952-1957 | Private general practice |

HONORS:

| | |
|---|---|
| 1986 | Alpha Omega Achievement Medal Award |
| 1986 | Goldstein Lecture, Emory University |
| 1985 | Benjamin J. Robinson Lecture, Maryland University |
| 1984 | Alfred C. Fones Medal for Outstanding Achievement in the Service of Humanity, Connecticut State Dental Association |
| 1983 | International Award of the Friends of the University of Connecticut School of Dental Medicine |
| 1983 | Lister Hill Memorial Lecture, University of Alabama, Birmingham |
| 1983 | Daniel F. Lynch Award, Dental Society of Greater Waterbury, Connecticut |
| 1983 | International Lecturer of the Year Award, Academy of International Dental Studies |
| 1982 | Gold Medal, University of Ghent, Belgium |
| 1982 | Centennial Award, University of California School of Dentistry, San Francisco |
| 1982 | Award of Merit, Hartford Dental Society, Connecticut |
| 1979 | Irving Glickman Memorial Lecture, Tufts University, Boston, Massachusetts |
| 1978 | William J. Gies Award, American Academy of Periodontology |
| 1977 | Arthur Merritt Memorial Lecture, Baylor University, Dallas, Texas |
| 1976 | Certificate of Achievement, Connecticut Society of Periodontists |
| 1973 | Massachussetts Dental Society International Award |
| 1972 | Honored by Her Majesty the Queen of Denmark (Knight of Danebrog) |
| 1972 | American Society of Preventive Dentistry International Award |
| 1969 | International Association for Dental Research Award for Basic Research in Periodontics |
| 1969 | Aalborg Dental Society Prize of Honour, Denmark |
| 1965 | Erik Berg Foundation Prize of Honor, Copenhagen, Denmark |
| 1959 | Ingv. Stokke Prize for Outstanding Dental Research, Norway |
| 1959 | Norwegian Dental Association 75th Anniversary Prize |

HONORARY MEMBERSHIPS AND FELLOWSHIPS:

| | |
|---|---|
| 1985 | Member, National Academy of Sciences, Institute of Medicine |
| 1984 | Honorary Member, Norwegian Dental Association |
| 1982 | Honorary Member, Belgian Periodontal Society |
| 1982 | Honorary Member, Societe Francaise de Parodontologie |
| 1982 | Corresponding Member, Swiss Periodontal Society |
| 1981 | Honorary Member, Scandinavian Society of Periodontology |
| 1981 | Fellow, American Association for the Advancement of Science |
| 1980 | Fellow, American College of Dentists |
| 1978 | Fellow, International College of Dentists |
| 1978 | Honorary Member, Centro de Estudios de Recursos Odontologicos pera el Nino |
| 1976 | Honorary Member, Horace Wells club, Hartford, Connectucut |
| 1974 | Corresponding Member, Finnish Dental Society |
| 1972 | Honorary Member, South African Society of Periodontology |
| 1970 | Honorary Member, Cercle de Parodontie, France |
| 1969 | Honorary Member, Western Society of Periodontology, Denmark |
| 1968 | Honorary Member, Colombia Society of Periodontology, Colombia, South Africa |
| 1966 | Corresponding Member, Swedish Dental Association |
| 1965 | Honorary Member, Milwaukee Dental Forum, Wisconsin |

PUBLICATIONS:

Author of more than 245 publications

Lectured in Argentina, Austria, Australia, Belgium, Brazil, People's Republic of China, Colombia, Denmark, Finland, France, Germany, Greece, Holland, Iceland, Israel, Italy, Japan, Mexico, New Guinea, Norway, South Africa, Sri Lanka, Sweden, Switzerland, The United Kingdom, The United States of America, Yugoslavia.

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## STATEMENT OF DENNIS P. WILLIAMS

Since its inception in 1974, the National Institute on Aging (NIA) has served both as a key resource and a major catalyst in advancing knowledge about the processes of aging and the diseases and disorders commonly encountered as one grows older. Significant progress has been made in research on aging over the last 14 years, and many stereotypes of aging -- such as the myth that loss of mental function is an inevitable consequence of growing older -- have been shown to be false. Opportunities for new insights into the aging process now exist through the use of sophisticated molecular biological techniques; studies of the etiology, diagnosis, and treatment of Alzheimer's disease are leading to a better understanding of this disease; and research on nutrition, exercise, and health maintenance in older people, aiming to improve the quality of life and to contain the costs of health care and dependency, are taking on new importance.

Molecular biological techniques should prove very valuable in testing theories of aging and uncovering causal relationships during aging. The use of these techniques has already provided promising leads toward understanding aging. For example, statin, a protein associated with changes that occur in cell cultures as they age, has been identified, and the gene coding for this protein has been cloned. Future work will focus on sequencing the gene, characterizing the protein, and determining the function of the protein and the control of its expression.

Other very promising research at the molecular and cellular level indicates that age-related changes in calcium ion regulation within cells may constitute a common underlying mechanism for such diverse pathologies as heart failure, nerve cell death, and memory impairment. Further understanding of the role of calcium in aging is expected to lead to the development of new, more effective strategies of disease prevention and treatment in age-related disorders.

It is estimated that etween 2.5 and 3 million people in the United States have Alzheimer's disease, and that the total cost of their care is nearly $90 billion per year. This past year, several provocative advances have occurred which have enhanced the prospects for an ultimate understanding of genetic and other causes of Alzheimer's disease, and a potential treatment for some of its most serious symptoms.

Scientists affiliated with a number of research institutions have announced finding the gene responsible for production of amyloid protein, a pathological "marker" associated with Alzheimer's disease. The amyloid protein gene is located on chromosome 21. In addition, in a group of families in whom Alzheimer's disease is highly inherited, the location of the gene(s) associated with this disease has also been found to be on chromosome 21, although not in exactly the same site as the gene responsible for the amyloid protein. Such studies are stimulating further research on the molecular genetics of Alzheimer's disease, on the molecular identification of the gene locus involved in the etiology of Alzheimer's disease, and on the potential of the use of a genetic marker for those at risk for Alzheimer's disease.

Advances have also been made toward early and accurate detection of Alzheimer's disease (AD). Recent research, for example, indicates that sensory deficits often are the first neuropsychological impairments to occur, preceding all other cognitive deficits. Non-invasive diagnostic instruments, such as Positron Emission Tomography and Magnetic Resonance Imaging, have created the potential for detecting and studying biochemical, structural, and membrane changes in the brain. Recently, scientists have identified positive biological markers for AD, such as the presence of a unique abnormal protein, A68, in the brain and cerebrospinal fluid of AD patients.

Finding a treatment for Alzheimer's disease is one of NIA's most important priorities. After Dr. William Summers published his findings on THA in November 1986, the NIA, in collaboration with the Warner-Lambert Company and the Alzheimer's Disease and Related Disorders Association, was quickly able to initiate a full scale clinical trial on the safety and efficacy of THA through its Alzheimer's Disease Research Centers. I am pleased to report to you that the trial -- temporarily suspended in October, 1987, due to abnormal elevations of liver enzymes in patients exposed to the two highest doses of THA -- was resumed this February using a modified protocol. It is expected that definitive information on the efficacy of THA will be available by spring, 1989.

In 1987, the NIA issued a Request for Applications for a competitive, congressionally-mandated award program for senior biomedical researchers in the field of Alzheimer's disease research. These "Leadership and Excellence in Alzheimer's Disease" (LEAD) awards will allow recipients to devote a major portion of their time to research and to assisting in the development of outstanding junior biomedical investigators interested in Alzheimer's disease and other dementias of aging. The Congress also provided authorization for the NIA to establish a clearinghouse to gather, maintain, and disseminate information about Alzheimer's disease. The NIA has now contracted with a consortium of organizations to develop a bibliography and resource guide of existing materials and programs, and a strategy plan to implement the Education Center. A draft report has been completed on the current level of knowledge and attitudes among the general public concerning AD. The findings and recommendations of this report were presented and considered at the Alzheimer's Disease Education Center Planning Conference held January 25-26, 1988.

Two NIA programs -- the intramural Epidemiology, Demography, and Biometry Program (EDBP) and the extramural Neurosciences and Neuropsychology of Aging Program (NNA) -- are working cooperatively to develop a series of cross-cultural and cross-national research projects on the epidemiology of Alzheimer's disease and related dementias. Co-operation between these two programs will ensure complementarity of research projects. Emphasis will be placed on the establishment of such studies in populations of Asian, Pacific, European and Black ancestry, both within the United States and in other nations.

Loss of the ability to function effectively in everyday life is probably the central factor precipitating the need for caretaking and other services by the older population. Understanding the trajectories of decrements in the ability of older people to function in everyday life, and identification of risk factors, are essential first steps for the development of appropriate prevention and intervention programs. For the past five years, the NIA has supported Established Populations for Epidemiologic Studies of the Elderly (EPESE). Preliminary analysis of data collected on hospitalization, institutionalization, and death has highlighted the importance of comprehensive studies of the panoply of disease and disability often borne by older persons, in addition to studies of each disease or disability in isolation.

Behavioral and life-style factors are known to be major causes of illnesses. NIA-supported research is specifying links between health outcomes and how older people perceive their health, how they engage in self-care and use formal health care organizations, and how they cope with chronic diseases and disabilities. Targeted for attention are such topics as injury prevention, rehabilitation, reduction of long-term care needs, and the implications of the AIDS epidemic.

As many as 3,500 older persons may be among the unfortunate individuals who received blood transfusions contaminated with the AIDS virus before this risk was recognized. The potential interactions of aging and AIDS on the immune systems of these individuals should be investigated. Other NIA AIDS research will focus on such issues as older people as caretakers of AIDS victims, the potential impact of an AIDS epidemic on the age structure of the population, and the impact of beliefs about AIDS upon sexual behaviors over the life course.

Nutrition is one of two life style factors -- the other being exercise -- that form the cornerstone of health promotion. Nutrition almost certainly plays a mitigating role in many, if not all, chronic diseases common in old age as well as many aging systems. Findings of causal relationships among nutritional status, disease, and aging systems would therefore be very valuable. In 1987, the NIA expanded its program on nutrition and aging. The program's foundation is built on studies designed to define the nutritional requirements for good health in older people; determine how dietary deficiencies are associated with depressed immunity, depressed cognitive function, or overt metabolic disease; and how eating behaviors change with age. In this context, the NIA plans to supplement the upcoming National Center for Health Statistics' Health and Nutrition Examination Survey (NHANES III), which will allow the NIA to gather additional dietary intake information on all respondents over the age of 60.

A program of international and cross-cultural studies is taking shape within the NIA. The coordinating unit for the World Health Organization (WHO) Special Program for Research on Aging will be housed within NIA and will work in close association with NIA staff. The NIA is planning cooperative epidemiologic efforts with WHO, the Agency for International Development, and other institutions to examine, summarize, or supplement existing data sets. In a parallel effort, NIA epidemiologists have met with their Italian counterparts, and are planning a collaborative effort to compare aspects of dementing and disabling illnesses among older residents of southern Italy and relatives who migrated to the United States. A separate initiative, utilizing the on-going Honolulu Heart Project supported by the National Heart, Lung, and Blood Institute (NHLBI), is planned to encourage cross-cultural investigations on age-specific incidence rates, prevalence rates and risk factors for Alzheimer's disease. In addition, it may be possible to compare Japanese-Americans participating in this study with Japanese living in Japan.

Providing training and experience in aging research remains a high NIA priority. The congressionally-mandated report, Personnel for Health Needs of the Elderly Through the Year 2020, has been completed and copies have been distributed. Findings include the fact that shortages of faculty members and other leaders with adequate preparation in aging and geriatrics are a serious constraint on the development of further activities in research and professional education programs. The current number of prepared teaching faculty and investigators in various professional and scientific fields ranges from 5 to 25 percent of total estimated needs.

A recent Institute of Medicine (IOM) report, entitled "Academic Geriatrics for the Year 2000," recommended establishment of Centers of Excellence to promote development of leaders in geriatrics. Following IOM advice, the NIA is currently developing plans to establish up to ten Centers of Excellence for Research and Training to help generate the needed leadership as rapidly as possible. The mission of these new centers will be to provide structured training in a strong research setting.

I would like, as a final note, to mention that the body of knowledge in the field of aging research has progressed to the point that it is now practical to undertake clinical trials and health promotion projects in a variety of areas. In addition to the THA clinical trial in Alzheimer's disease already referred to, NIA is supporting and conducting clinical trials in such areas as the benefits of exercise in minimizing bone loss and the likelihood of diabetes, in prevention of falls, and in the management of urinary incontinence.

Mr. Chairman, the 1989 budget request for this Institute is 204,770,000. I will be happy to answer any questions.

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## BIOGRAPHY OF DENNIS P. WILLIAMS

Birthdate: November 26, 1921 - Belmont, North Carolina

Education: B.S., University of North Carolina, 1942; M.A., Columbia University, 1943; M.D., (Cum Laude) Harvard Medical School, 1950

Professional History: 1963 to present, Director, National Institute on Aging, NIH, 1983, J.Lowell Orbison Alumni

Distinguished Service Professor; 1982-1983, Director of the Geriatric Unit, Monroe Community Hospital, Rochester, N.Y.; 1980-1983, Co-Director, Center on Aging, University of Rochester Medical Center; 1968-present, Professor of Medicine and of Preventive, Family and Rehabilitation Medicine, University of Rochester; 1968-1982, Medical Director, Monroe Community Hospital, Rochester, N.Y.; 1977, L.S. Mcleod Visiting Professor of Geriatric Medicine, University of Adelaide and South Australia Postgraduate Medical Education Association; 1956-1968, Instructor to Professor of Medicine and of Preventive Medicine, University of North Carolina; 1954-1956, Fellow in Medicine, University of North Carolina; 1953-1954, Assistant in Medicine, Boston University; 1953-1954, Senior Resident Physician, Boston Veterans Administration Hospital; 1950-1953, Intern and Assistant Resident Physician, John Hopkins Hospital; 1942-1943, Assistant in Chemistry, Columbia University.

Military Service: 1983 to present, Assistant Surgeon General, U.S. Public Health Service; 1943-1946, Communication Officer, U.S. Naval Reserve, active duty.

Societies and Associations: American Association for the Advancement of Science (Fellow); American College of Physicians (Fellow); American Federation for Clinical Research; American Public Health Association (Fellow); American Society of Human Genetics; American Geriatrics Society; American Diabetes Association; Society for Experimental Biology and Medicine Rochester Academy of Medicine; New York and Monroe County Medical Societies; Gerontological Society of America; New York State Public Health Association; Institute of Medicine, National Academy of Sciences; The Royal Society of Medicine; and Academia Medicorum Litteratorum.

Honors and Awards: Phi Beta Kappa; Alpha Omega; Sigma Xi; Member, Institute of Medicine; Diplomate, American Board of Internal Medicine; Diplomate, National Board of Medical Examiners; Markle Scholar in the Medical Sciences; Special Fellow, Department of Physiocoloy, Vanderbilt University; and Honorary Member, American Academy of Orthopedic Surgeons.

Publications: Author of over 112 scientific papers and abstracts.

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## STATEMENT OF DR. CARL KUPFER

About one-half million legally blind Americans cannot read, drive, enjoy a movie, or do many of the activities that we with sight take for granted. Another 10 million have impaired vision. It is difficult to express the costs of vision loss in human terms, but those for professional care and special services alone are an estimated $16 billion each year. The mission of the National Eye Institute (NEI) is to encourage and support research that will spare people from the threat of visual disability and that will reduce the social and financial burden that eye diseases impose, not only on the visually impaired and their families, but also on the entire Nation.

We recently had the pleasure of announcing the first effective treatment for a disease that threatens the vision of very small premature infants. The disease, called retinopathy of prematurity, annually causes vision loss in

2,600 infants in the United States. Cryotherapy, or freeze treatment, applied with a small cryoprobe to the outer surface of the eye near the front, slows or stops the excessive branching of blood vessels inside the eye. These abnormal vessel clusters damage the retina and may lead to retinal detachment and blindness. The NEI-supported investigators found that cryotherapy reduces by one-half the risk of severe visual loss from this disease. Although we must follow the long-term results of the therapy, these findings represent the most significant treatment advance since the disease was first recognized more than 40 years ago.

Many of our basic research investments have also come to exciting fruition. Just two years ago I told you about research aimed at regenerating damaged nerves of the visual system. This past year we have made some significant progress toward that goal. NEI-funded scientists, in work with implication for nerve regeneration in the visual system, have demonstrated that crushed nerve fibers in animals can be made to regenerate and become functional. In their initial work, they used nerve connections in limbs because they are more accessible for experimental implants than eye tissues.

To form a bridge to support the regenerating cells, they used porous cellulose strips that were impregnated with immature glial cells, the cells that support nerve tissue function. This glial bridge induced nerve fibers adjacent to the crushed nerves to grow across it and make the appropriate connections with the spinal cord. About half the adult rats in the experiment regained sensation and function in the limb with the crushed nerves. It appears that the glial implant facilitates regeneration first, by guiding the growing nerve fibers and second, by impeding the formation of scar tissue that normally blocks regrowth of peripheral nerve fibers. With this understanding, the scientists are now investigating whether optic nerve regeneration can be induced with similar methods.

Other neurobiologists working in the visual system are studying growth-associated proteins, or GAPs. These growth proteins are active only in nerve fibers that are capable of nerve regeneration, such as those of the central nervous system in lower vertebrates like fish and amphibia, the peripheral nervous system of mammals, or the central nervous system of very young mammals. At present we do not know how to activate GAPs in nerve fibers that do not readily regenerate, such as those in the central nervous system of more developed mammals. With the discovery of these proteins, we now have a laboratory tool to study the molecular processes underlying nerve regeneration. Our goal is to induce the expression of GAPs in nerves that do not normally regenerate, such as the optic nerve.

Another field of basic research that has been producing exciting results is molecular genetics. Last year I reported that NEI-funded scientists had isolated the gene associated with the rare but devastating childhood eye cancer, retinoblastoma. That was the first finding of a cancer gene that works in reverse of the other known cancer genes--its nonfunction is what prompts the development of cancer. On the basis of this discovery, the scientists have recently developed a simple blood test to identify which children in families with a history of retinoblastoma are at risk of developing the hereditary form of the disease.

Those children found to carry the defective gene can be monitored in order to detect the cancer before it progresses to the stage at which the only treatment option is removal of the eye. These children can also be monitored for early signs of other cancers for which patients with retinoblastoma have an increased risk, namely, osteosarcoma and certain radiation-induced cancers. On the other hand, children who do not inherit the cancer gene can be spared the ordeal of being examined under anesthesia every three months until they are past five, the age at which the greatest risk for this childhood cancer is over.

Research in ocular immunology has also continued to produce excellent results. One area of investigation that has provided a high return on dollars and manpower invested is research on a group of inflammatory disorders called uveitis. Uveitis is an inflammation of the middle layer of the eye, which extends from the colored iris in the front to the retina-nourishing choroid in the back. If certain uveal diseases are not treated, they can later destroy retinal cells, causing loss of vision.

For years it has been suspected that some uveal diseases are autoimmune, meaning that the immune system mistakenly identifies some of the body's own tissue as alien and attacks it. In fact, some researchers now believe that autoimmunity is a major factor in as much as 60 percent of certain types of uveitis. However, until recently, the how and why of this autoimmunity were not clearly understood. Now, the progress we are making in understanding and treating immune uveitis is remarkable.

Less than a decade ago, an NEI-funded scientist found that some uveitis patients have white blood cells that react against a natural retinal protein as if it were a foreign invader. Standard treatment with corticosteroids to reduce inflammation does not work well with these patients. Because the white blood cells involved in the immune reaction are the same T cells that cause the body to reject a transplanted organ, NEI intramural researchers selected cyclosporine A as a possible treatment for these patients. This drug has been used very successfully in preventing the autoimmune rejection of donor organs such as kidneys.

The researchers found that with cyclosporine therapy, the uveal inflammations rapidly decreased, sometimes within 24 hours. But what is even more significant, the visual acuity of most patients actually improved during the first 10 days of treatment and continued to improve for 6 to 8 weeks more in some cases. This pilot study has led to a full-scale clinical trial comparing corticosteroid therapy to cyclosporine A, either alone or in combination with a corticosteroid.

Because a drug used against an autoimmune disease must be taken for a lifetime, the NEI scientists are looking for other treatments that will be as effective as cyclosporine A, but without the attendant risk of kidney toxicity from the high-dose cyclosporine needed for effectiveness. Bromocriptine is a drug that suppresses the secretion of prolactin, a hormone that interferes with the action of cyclosporine in two ways: it activates the immune system and it also prevents the cyclosporine from binding to the aberrant T cells that attack the ocular tissue. When bromocriptine is used in combination with the immunosuppressant, lower, safer doses of cyclosporine are required to bring about the same therapeutic results. Our scientists are also testing cyclosporine G, another immunosuppressive drug that seems to have lower kidney toxicity.

This research has some exciting implications beyond its potential benefit for uveitis. The combination cyclosporine and bromocriptine therapy may enable scientists to understand better how the endocrine system interacts with the immune system and thus improve treatment of other autoimmune inflammatory diseases.

Another potentially blinding inflammatory disease, presumed ocular histoplasmosis, is thought to be caused by a fungus that grows in the soil. The histoplasmosis fungus is found most often along river valleys in the so-called "histo belt," which includes all of Arkansas, Kentucky, Missouri, Tennessee, West Virginia, and major portions of 13 other states. When contaminated soil is disturbed, the fungal spores can be inhaled, sometimes causing a lung infection, similar to a mild influenza attack.

Occasionally the organism moves to the eye where, after infection, it leaves tiny scars or histo spots on the choroid, the vascular layer of tissue that nourishes the retina. Most of the time the spots remain quiescent and present no problem. Even if they do become inflamed, because they are often located in the peripheral areas of the retina, central vision is not affected. However, if any spots beneath the central macula become inflamed and develop weak blood vessels, these blood vessels and the fluid they leak can progressively destroy vision. This is especially true if the vessels push against and damage the fovea, the area of the retina responsible for the sharpest central vision.

An NEI-sponsored multicenter clinical trial reported in 1983 that the argon blue-green laser can be used successfully to seal the leaking vessels of presumed ocular histoplasmosis if the vessels are located a certain distance from the foveal area. To seal the vessels beneath the foveal area without damaging the very sensitive overlying retinal tissue, the laser must have a highly focussed wavelength that will reach the vessels without being absorbed by retinal pigments. When the krypton red laser became available, the trial was expanded to include that device, which produces a longer wavelength, is not affected by the pigment, and can be brought to a very fine focus. Just five months ago the study researchers reported that the krypton laser can be used to treat patients who were excluded from argon treatment not only because of blood vessel location, but also because of heavy hemorrhaging or hypertension.

In fact, the krypton laser treatment proved so effective after three years of followup, the study investigators began treating the eligible eyes of each patient that had been left untreated as controls. The researchers continue to evaluate the long-term results of this new therapy, but in the meantime, the sight-damaging effects of ocular histoplasmosis can be arrested in many patients ineligible for argon laser treatment. The same clinical study is also investigating the krypton laser for treating leaking blood vessels in the devastating age-related macular degeneration and other macular diseases of unknown origin.

To encourage patients and researchers to participate in clinical trials, this past November the NEI published a booklet describing its 17 ongoing clinical trials that cover all of the five major disease programs of the NEI. The booklet, which will be updated regularly, summarizes each trial's purpose, background, patient recruitment status, and patient eligibility, and provides a list of any published trial results. Practitioners can use this information to refer patients who may benefit from the specialized treatment that the trials provide and to encourage their already enrolled patients to return for followup visits.

Lastly, I am pleased to tell you today of our plans to develop a National Eye Health Education Program. Over the years, Congressional committees and the National Advisory Eye Council have urged the NEI to develop programs in eye health education, eye disease prevention, and education in coping with low vision, but funds were never appropriated for this specific task. Our FY 1988 appropriation, however, includes $1.1 million and up to 10 positions for NEI to "increase its public and professional education activities relevant to the prevention of blindness and to intensify its applied research effort that produces new information to be disseminated."

We plan to use these funds and positions to develop a glaucoma education and applied research program, emphasizing the importance of early detection and of determining factors that increase a person's risk for developing glaucoma. We also plan to launch a full-scale effort to increase public and health professional awareness of research results that can be applied to preventing blindness from diabetic retinopathy.

In many ways we are now reaping the benefits of research set in motion years ago. But with the recent rapid advances in biomedical technology and the more precise understanding of disease mechanisms gained through the basic biosciences, future clinical advances should be even more impressive. The results of the research momentum in prevention, diagnosis, and treatment of ocular diseases we cannot predict or even imagine.

Mr. Chairman, the 1989 budget request for the National Eye Institute is $229,021,000. I will be pleased to answer your questions.

### CANCER INCIDENCE AND MORTALITY

Senator CHILES. We hear so many reports from cancer statistics that it is hard to know what progress is being made.

We know that the incident rate of those over 55 years of age is increasing and the death rates have increased 7 percent since 1980. We know that deaths from lung cancer have increased 43 percent among white females since 1950.

We know the total number of people who die from cancer each year continues to grow, and then we hear encouraging statistics such as that 50 percent of all cancer patients can now be cured. And if we exclude lung cancer, mortality has declined 14 percent since 1950.

I know at the committee's request you have convened a panel of experts to recommend measures, serious measures, that are most appropriate to assess the progress of cancer. Tell the committee how you interpret the many cancer statistics, and what is your view of the progress that we are actually making?

Dr. DEVITA. First of all, we thank you for the request to convene that committee.

The committee in fact has met, I have seen a draft report. It is a really fine report, and will be very useful. You will be getting it, I believe, in June.

And what they point out, and what we all have to deal with, is that the mortality statistics are the end of a funnel. They are the very last measure to change, and the measure you really want to see impacted by any research in the field.

But in this country from the time of the new discovery to the time that you impact on mortality statistics, it takes about 10 to 15 years, unfortunately.

For example, the first adjuvant breast cancer studies that were reported as positive were in 1974. Now 14 years later we know that every woman with breast cancer should go on some form of adjuvant therapy.

We should be able to decrease mortality in this country from breast cancer by 30 percent by applying all that therapy, and another 30 percent by applying mammography. So we have the tools within our grasp to make a real big hit on breast cancer.

We had them in our hands in 1974. But it takes a lot of pulling and tugging and refurbishing the data to get people to accept the information and use it very widely. And I confess that we are very frustrated by the slowness in the translation of some of this information to practical use.

We are also frustrated, Mr. Chairman, by the fact that total numbers of cancer deaths are sometimes confused with the absence of any progress in declining mortality. Let me give you an example.

If we had 100 people in the country in 1950, and 10 out of 100 died of cancer the rate would be 10 percent. In 1980, if the population doubled to 200, you would have 20 out of 200 people dying of cancer if the mortality rate remained 10 percent. So, even though the mortality rate was the same in 1950 and 1980, more people would die in 1980 because of the increase in the size of the general population.

Now if you develop a treatment that, say, reduced mortality from cancer by 25 percent, and you make the same comparisons, you would have 10 patients dying out of 100 in 1950, but you would have 15 out of 200 in 1985, This would be a 25-percent decline in mortality but a 50-percent increase in the number of deaths, all due to the increase in the size of the population.

So if you would happen to want to be critical, you can say more people are dying of cancer, and that obscures the fact that lots of progress has been made, but you cannot see it if you look at total numbers.

We are impressed by the age-specific mortality data where below the age of 55 we are seeing significant declines. And if you pull lung cancer out, as you have, Mr. Chairman, the decline in mortality goes all the way up to the age of 85.

We have an epidemic of lung cancer that is beginning to turn around due to smoking cessation. Lung cancer does obscure a lot of the progress. This will all be in the report to the committee, and I think, and hope, you will be pleased with it.

## CANCER PREVENTION AND CONTROL

Senator CHILES. Well, I want to compliment you on your commitment to the goal of reducing the cancer death rate by 50 percent by the year 2000.

And I understand this can be achieved by reducing that rate of smoking and improving and changing the American diet, better screening and early detection and the use of state-of-the-art treatment.

But you referred to this, and I have great concern with the recent GAO report entitled, "Applications of Breakthrough Therapy." It reported up to two-thirds of cancer patients are not getting state-of-the-art treatment.

How in the world do we encourage physicians to understand and use the state-of-the-art treatment? And I notice that the mission of the Cancer Prevention and Control Program is to assure the application of the results of cancer research. That effort is proposed to be funded at $71.3 million, less than 5 percent of the cancer budget.

If we already have enough medicine that we know about to reduce cancer by 50 percent, as stated by the year 2000 goals, should we not be spending more on making sure that that medicine is being used and those techniques are being used, and that we are getting that out to assure that the population has a shot at it?

Dr. DEVITA. Well, we agree with you. That is a neglected area of our budget.

I am afraid that it is my fault in the sense that when I come and tell you about what we are doing in prevention, I don't always make it clear that many activities are funded out of the cancer prevention and control budget. We have 38 clinical trials testing various ways to prevent cancer. And Mr. Chairman, I tell you, when one of those studies becomes positive you are going to hear about it, because it is going to create a revolution in prospective prevention. Those are all funded out of the cancer control budget.

When we talk about them, I think most of the time people assume they are in the research project pool where most of the resources go. They are not. They and other applied prevention studies are in the cancer control line.

And that line has not increased as much as the rest of the budget. This has been somewhat frustrating for the people who are developing the prevention studies. That is one answer.

The other answer is a bit more troublesome in that it has nothing to do with budget. And that is, we have absolutely no control, nor should we, over the practice of medicine. All we can do is jawbone, and we do have campaigns underway to educate the public on the values of clinical trials and so forth.

We cannot go out and tell doctors, this is the way you should practice medicine. There has always been this give and take amongst physicians about willingness to accept a new approach to therapy, especially when it moves the treatment of a disease from their specialty to another specialty. It has an economic impact on the practice of medicine. And that has slowed the breast cancer progress down.

Today women can get lumpectomy and radiation therapy as the primary therapy and then adjuvant therapy. They look normal, they feel normal, and they live longer. But 15 years ago, the data was already very good that we should treat patients the way we treat them today.

But the economics of medicine did not allow the switch between the radical mastectomy and the rather simple local control and adjuvant chemotherapy. Those are complex problems.

Facing up to the goals for the year 2000, however, had a big positive spinoff, because it had forced us to examine all our own machinery to see if it could meet the goals. And some of it needs repair.

And it forced us to face up to the fact that there are things out there we have no control over that will stand in the way of reaching the goals, unless we do something. And the something we do is talk about it, and get it on the national agenda as often as we can.

I think we have done a pretty good job of that. We have a rather large cancer communications program.

## STATE-OF-THE-ART TREATMENT INFORMATION

Senator CHILES. Well, I am trying to understand that answer. And I hear what you say, that you cannot tell a doctor how to practice medicine.

On the other hand, from the standpoint of us that sit up here and determine the dollars that we are spending and putting out, and we have certainly tried to do that, and recognizing that there is great enthusiasm to continue to find and discover, as there always is, I think we do have the responsibility up here, maybe different from yours, but we have got to figure out how to do that.

Because to think that we are spending this money discovering all of these new ways, and that we have got literally thousands of people that may be dying because they are not getting the ways that are out there now, I do not think it is acceptable for us to say that we cannot affect the practice of medicine. I do not believe that is a good enough answer.

I am not satisfied to give that answer myself. That is what I am saying.

Dr. DEVITA. Yes; you probably are aware of our PDQ system, which is a computerized cancer information system. It provides state-of-the-art treatment information for all cancer, all research protocols, all geographically matrixed, so anybody anywhere can locate an appropriate study.

That was our attempt to impact on the practice of medicine so that the people could go and find out who is the best person and what they are doing and where they are. It is up and running and its use is going up 20 percent per year, and we are very pleased.

But it has been a difficult interface with the practice of medicine for the very reasons I mentioned. The doctors say, you are trying to change referral patterns, and you are trying to interfere with the practice of medicine. And we have gone about as far as we can go with our own authority.

I think having the opportunity to discuss it at hearings and have the Congress aware of this is of additional value in opening up the public's mind to some of the difficulties that we face.

## SURVIVAL BY RACE

Senator CHILES. I note in your budget justification the overall survival rate for cancer is 50 percent for whites compared to 37 percent for blacks.

The Cancer Institute is mounting a number of programs to improve this state of affairs. Tell us more specifically what you are talking about there.

Dr. DEVITA. The program that we set up as part of our network to monitor the national incidence and survival and mortality rates samples about 12 percent of the country, and a substantial part of the black population. And that is how we uncovered the rather large discrepancy between survival rates.

Since then we have set up some 20 programs now running about $35 million a year that are aimed at minorities, first of all to study the reasons why this avoidable mortality is occurring.

We have several studies underway looking at control caucasian populations and black populations with the same tumor types, to look at whether it is stage at diagnosis, kind of treatment, and so forth, to pinpoint the reasons for the decreased survival.

We have also begun to set up training programs specifically aimed at minorities. Our clinical trials apparatus has been extended in a satellite program to hospitals, with large numbers of minorities.

We are adding special supplements to our grant programs for minority investigators, so that a minority investigator can be added to a grant without having to go through the standard peer review process. We can give them access to training. Because many of the totally black medical schools have not got the personnel to handle some of the problems that they need to face, we have also set up a consortium grant of all the black medical colleges in the country. This planning grant which is now going into a center consortium grant, will enable them to deal effectively with the problems of blacks and minorities.

And we have established a Black Prevention Awareness Program that is involved with a number of organizations that deal with the black community throughout the country. It now numbers over 2,200 organizations.

We cannot get up and say, we have a problem with the black population, here is how we think you should solve it, because no one will pay any attention to us at all.

So we are trying to go directly into the community through a special populations branch we have in our Institute to deal with minority populations. We have focused on blacks because blacks have the biggest problem of all the minorities.

But we have founded programs in other minority populations. American Indians, for example, where they also have a problem.

Hispanics have some problems in survival, but in fact their incidence and mortality rates are lower than the other groups in the country, probably because of the risk factors like diet that influence their cancers. You have a reverse problem. You have to say to them, listen, you are doing something well, do not change it.

Basically we spent the first part of this century getting the first 50 percent cured. The second 50 percent of cancer patients is proving difficult enough.

However, we cannot deal with the deficits in the first 50 percent, which is 37 percent survival rate for blacks without setting up a series of programs as we have done. You have got to get them up and equilibrate them with the caucasian population.

Senator WEICKER. I must confess, I do not find anything so unbelievable about the fact there is a lower survival rate. Is there not a higher infant mortality rate among blacks than there is whites?

Dr. DeVita. Sure.

Senator Weicker. Less of a diabetes cure among blacks than there is against whites? Or heart cures, or whatever? I mean, hey, does it not have something to do with the availability of decent medical care for the minority population?

Dr. DeVita. I am sure it does.

### AIDS AND PRECLINICAL DRUG DISCOVERY

Senator Weicker. Then you get beat over the head when you suggest that maybe 38 million Americans that have no health insurance ought to have some sort of minimal health care, prenatal care, et cetera. Believe me, nobody wants to even think about that.

During the past year, the National Institutes of Health have established a major program for AIDS drug discovery, with NCI having the primary responsibility for preclinical drug discovery and development. Am I correct on that?

Dr. DeVita. Yes.

Senator Weicker. What is the significance of the program for our ability to test AIDS drugs in clinical trials, and how much are you spending in this area in 1988?

Dr. DeVita. The whole NCI drug effort in AIDS comes to about $42 million of the $125 million. We are now testing about 250 compounds a week in the screening program. A couple of very exciting leads have been identified.

And as I think Dr. Wyngaarden mentioned in his opening statement, we now have a greater capacity in the Clinical Center to do the earliest studies on the compounds that come out of the drug development network by the opening of some additional beds for the Cancer Institute.

The most important observation is that it looks like you can find drugs. We know that. We have AZT and compounds related to AZT. But also we have a couple of other compounds that are completely different than the AZT model that will soon be coming up for testing.

So I am optimistic, as I have always been, that with the target being so specific we ought to be able to find drugs that can inhibit the virus and its spread.

### NATIONAL AIDS POLICY

Senator Weicker. Now, you are operating at the present time under a system whereby this money, your AIDS money is under your control, or under NIH in your control. Right?

Dr. DeVita. At the moment, yes.

Senator Weicker. At the moment.

Dr. DeVita. That is correct.

Senator Weicker. That is what is being done now.

Dr. DeVita. Yes.

Senator Weicker. How do you view this proposition of the money being under the Assistant Secretary of Health?

I mean, I think this is rather important because the proposal is out here. And we are going to be asked to pass upon that proposal.

And I think it is fair to say that, you know, I would like to hear the opinions of the people that are going to be impacted. They are the ones that understand the delicate balances to the administration's supervision, research, the scientists that work under you, et cetera.

So I think it is terribly important that we do get a view here. And I realize that is a little touchy. But I do not know who else to turn to and ask the question. I would hope that each man in turn would answer this question as to how he views this proposal.

Dr. DEVITA. Well, I think there are two parts to that answer, Senator Weicker. The first is that everybody feels that we need to have national policy on how we deal with AIDS.

And the only way you can deal with national policy is to make sure that someone very high up in the system has some control over where the resources are being allocated, how they are being allocated, and whether or not we have big gaps and have enough money. That speaks in favor of centralizing the budgets and the control of the budgets.

The other side of the coin is that, my own personal view, and I know I have said this many times, is that you should keep authority and responsibility very closely linked. The people who have to make their decisions on a day-to-day basis should not be forced to have to go through a whole chain of command, through people who do not know as much about the particular problem, to get the job done.

And to the extent that you centralize budgets and do that, then you have a downside risk. We have been assured, and I think we have to accept that, that this is not the intent of centralizing the budget, and that we would operate the same way we are operating now, and would be able to do our work on a day-to-day basis.

If that is the case, then the centralization of the budget will not have any impact. If it is not, then they will probably hear us moan.

## SUPERCOMPUTER

Senator WEICKER. That is an honest answer, a good answer.

One last question, because I know the chairman wants to move on. I understand the supercomputer has been valuable to NCI's cancer research efforts. Are we currently utilizing it at full capacity?

Dr. DEVITA. It is being used at full capacity and we would like to upgrade. We have decided that at some point in time we are going to have to do that, whether or not we have to find our own funds to do it. Part of that facility may well have to just be reoriented. It is a very valuable piece of equipment.

Senator WEICKER. How long does it take from the time you order one of these to the time you get one?

Dr. DEVITA. Well, since the facility is up and running, it would not take very long to install it. The initial setup took us 1 year.

Once we had all the necessary approvals, it took us 1 year to build the facility sufficient to take this computer and its accoutrements, and get it all operating. But now it has been operating for almost 2 years.

## SEQUENCING THE HUMAN GENOME

Senator WEICKER. And we have got to move up.

Dr. DEVITA. We could use additional speed. I think Dr. Wyngaarden told the committee earlier, the work on the sequencing of the genome is very much facilitated by the availability of very high-speed computers.

We were approached by the Department of Energy 2 years ago to include this computer in the effort to sequence the human genome. We could use the increased speed of the newer supercomputers.

## CANCER VACCINE RESEARCH

Senator CHILES. In the initial clinical trials and experimental anticancer vaccine development, our researchers at George Washington University doubled survivor rates of early stage lung cancer patients.

I understand it is not a vaccine in the classic sense. It does not prevent the disease. But it helps the patient fight existing disease by increasing the immune response system.

What is the current status of this new form of treatment? And is it available to other types of cancer?

Dr. DEVITA. There are vaccines of a sort being tested in colon cancer. They are using pooled cells plus BCG, the tuberculous organism, as an adjuvant to surgery.

Those studies are underway. One study looks like it might have a trend toward a positive effect for the vaccine. There are studies like that in malignant melanoma going on, using material from the surface of the malignant melanoma cells as well.

And then there is Dr. Hollingshead's study, which I think is the one you are referring to at George Washington University.

There were a number of studies like that done a decade or so ago that did not give us any positive information, and the enthusiasm for them is not as high as it once was. But they are what we have underway at the present time.

That particular study has problems in the sense that the patient population under study has varied from report to report. And there is an argument about whether you can analyze the data correctly if you drop out certain populations for specific reasons, as investigators sometimes do.

Let me analyze it, but not include this particular group. And when we do it this way we see a positive result. When you put the whole group together you do not see a positive result.

There is a fair amount of debate going on about that particular study. The doubling of the survival which, if everybody agreed, would be a major change, is somewhat controversial.

## PAP SMEAR TESTING

Senator CHILES. It has been widely reported over the last year that the PAP smear, one of the most common laboratory tests in the United States, is also the most inaccurate.

It is estimated the test as it is currently being performed fails to detect roughly one in four cases of cervical cancer.

We have an estimated 60,000 women in the United States expected to develop cancer of the cervix in 1988. If detected early the disease is almost always curable. But approximately about 7,000 American women die of the disease each year. What in the world can we do about that?

Dr. DEVITA. I think those reports have increased the concern over quality control. Doctors really need to be sure that the laboratories they are using are, in fact, quite capable of producing a product. And that is one of the problems.

Lots of laboratories spring up and they cannot produce good quality. I know that the American College of Pathology has been working to see if they cannot set up standards for quality control to improve this.

Since then, however, there has been a report of the use of cervigrams, actual photographs of the cervix, to supplement PAP smears. They are easier, because a camera takes a picture. It is not a subjective kind of thing.

And the accuracy may be even higher than the PAP smear, which would be a useful addition to the PAP smear. But the PAP smear remains basically a very good, very simple test.

The fact that cancer of the cervix is very slow to go from its first phase to the invasive phase, and you have one or two cycles of PAP smears, is a very nice protection. You do not have to depend on one test.

Senator CHILES. What about the recommendation of the American Cancer Society that women aged 20 to 40 do not need the test but every 3 years after two consecutive annual tests?

Dr. DEVITA. We concur with that.

Senator CHILES. You do agree with that?

Dr. DEVITA. Yes; we do. This year, all guidelines for screening with a slight change in mammography, those of the ACS, all the other organizations, and the National Cancer Institute, are now equivalent.

Senator CHILES. Dr. Lenfant, we will go now to your statement.

## NATIONAL HEART, LUNG, AND BLOOD INSTITUTE

Dr. LENFANT. Thank you, Mr. Chairman. As you just heard, heart diseases have the unfortunate characteristic of being the first cause of death in this country, and of course we are concerned by that and working very hard to have them become the second, hopefully third cause of death, and perhaps even less than that.

I would like to take this opportunity to briefly tell you about some of the accomplishments that we have made this year.

First of all, we have completed a new study, which has definitely shown that the blood clot dissolving drugs, which I mentioned last year as the first line of treatment for heart attack, can now be used as a single treatment without any accompanying intervention.

The meaning of this study is that, first, the applicability of the drugs which are dissolving blood clots is greatly enhanced, and second, the treatment can be used much more frequently than we first thought possible.

This year, as you know, we have reported a study known as the physician health study, which has shown the effectiveness of aspirin to prevent coronary heart disease in some groups of subjects.

I should say that a lot of questions remain following this report. In a couple of weeks the Institute will convene a group of experts to discuss and assess whether this preventive treatment should be generalized.

A few months ago the Institute reported guidelines for the treatment of elevated blood cholesterol in adults at risk of heart disease. As you may recall from my previous presentation to this committee, blood cholesterol is one of the most important risk factors of heart attacks in adults, males and females.

The thing which is quite comforting to us is that these guidelines have been widely accepted and already we are beginning to see evidence that they are having an impact.

While in the cardiovascular area we are successful and we are making progress, I have to underscore that in the lung program of the Institute we are not as successful. Indeed, mortality from chronic obstructive lung disease keeps on increasing.

In fact it has increased 30 percent during the last 10 years, and it keeps on increasing approximately 3 percent per year.

Some basic research is opening some new leads that we are exploring, leads which may provide us with a treatment of the genetic form of pulmonary chronic lung disease.

In the blood area, I would like to highlight a new program that the Institute has initiated this year. It is an educational program about blood resources. The purpose of this program is to help preserve the blood supply of the country.

I would like to conclude this brief review of our accomplishments. The budget request for the Institute is $1,015,471,000, excluding AIDS. And the request for AIDS is $39,032,000. Thank you, Mr. Chairman.

## EDUCATION PROGRAMS

Senator Chiles. Thank you. The Institute has three relatively well-known education programs underway: The National High Blood Pressure Education Program, the National Blood Resources Education Program, and the National Cholesterol Education Program.

These programs are funded at approximately $6 million with 35 people devoted to them. This level of effort is matched by private groups and foundations.

What is the private level of support that also contributes to getting the word out? In view of the fact that 55 percent of U.S. deaths each year are cardiovascular, lung, or blood related, is this an adequate level of funding?

Dr. LENFANT. Indeed, the Institute sponsors the educational programs that you mentioned. They are governed by a board of representatives from voluntary and professional organizations which are interested in the subject matter.

Through these organizations and the private sectors, pharmaceutical or food industry as may be the case, additional support is provided for these programs to disseminate information and recommendations.

The contribution of the Institute, however, is absolutely essential for the running of these activities. And as you pointed out, in 1988 the overall commitment of the Institute for this program is approximately $6.5 million.

These moneys are coming from two categories within our overall budget. One is the contract category, which is also used for the support of our clinical trials and other development activities. The rest of the money is coming from the research management and support fund of the Institute.

All in all, there is no question that the Institute has great difficulties in supporting these programs. We believe that these programs are very important; the High Blood Pressure Education Program has been tremendously effective in reducing cardiovascular mortality during the last 15 years.

The Cholesterol Education Program, which began 3 years ago, already is showing evidence of success. The Blood Resources Education Program was begun this year, so it is too early to judge its impact. But we know that the entire blood banking community is behind this program and working with us, and that in itself is already proof of a great success.

### AIDS AND BLOOD TESTS

Senator CHILES. Senator Weicker?

Senator WEICKER. Thank you, Mr. Chairman. Unfortunately I have to leave here in just a few minutes.

But I did want to ask Dr. Lenfant, why is it so difficult to develop an AIDS test that is more accurate than the ones that we currently use? And are there efforts underway at NHLBI to develop more accurate tests?

Dr. LENFANT. Well, the tests that are available now detect antibodies; these tests are extremely reliable.

The problem is that if one person is infected by the virus, there is a window of approximately 2 months before the antibodies occur in the blood. The only way to detect contamination during that period of time would be to detect the virus itself. And this is a very difficult, costly, and lengthy procedure.

There is, however, a piece of good news which has recently been published. It is coming from the work of one of our grantees. A new technique called DNA amplification has been developed; it allows detection of minute quantities of nucleic acid coming from the virus in the blood. This technique, actually, is now being further developed by Eastman Kodak for commercialization and dissemination. If that works out in a satisfactory way, I think that there is great hope that within some period of time there would be a practical method to detect viral contamination during the window of time I mentioned earlier.

Senator WEICKER. I have further questions for response to the record, Mr. Chairman.

## CHOLESTEROL TREATMENT

Senator CHILES. Last October, Dr. Lenfant, the Heart, Lung, and Blood Institute issued a detailed set of recommendations for the treatment of cholesterol.

Based on a doctor's survey, it has been found that physicians are leaving untreated about one-half the people with high blood cholesterol levels for which the new guidelines recommend treatment.

I understand the Institute is accepting private money for a cholesterol education program. In view of the priority of cholesterol guideline effort, is the funding level for this program adequate?

Dr. LENFANT. When these guidelines were released, the question that came up was how to disseminate these guidelines.

The Institute was not in a position to effect this dissemination on the scale that was wanted.

A number of pharmaceutical companies and food producing companies pooled some of their resources together. In fact to the extent of $775,000, I believe. With this money they published our recommendations and distributed them to the practicing community.

It is my understanding that through this effort and with the cooperation from the pharmaceutical and food industries, nearly 140,000 practicing physicians have received these recommendations.

The interesting thing is that these recommendations already have an impact. We also know that many of the physicians who have not been part of this distribution are writing to us and saying: "We heard that you are distributing these recommendations; could we have a copy of them?" And unfortunately at this time this distribution has been interrupted.

Senator CHILES. You do not have enough to distribute?

Dr. LENFANT. Well, the cost of producing these kits and recommendations is high. And we have committed as much as we can commit to this activity.

Senator CHILES. Well, it would seem to me again that that is something that we ought to be providing the money for.

If we have got something, we know it will tremendously save and change lives, we ought to be trying to get that out there so the doctors can use it.

Dr. LENFANT. I would certainly agree with that.

## ASPIRIN AND HEART ATTACKS

Senator CHILES. We have heard a great deal about the new wonder drug, aspirin, and its beneficial effects on those with the risk of heart attack. Unfortunately, many of the early press reports suggested almost every American over age 40 should be taking an aspirin every other day.

What efforts has the Institute undertaken for education of the public with regard to the use of aspirin? And specifically with regard to who should be using aspirin as a moderating factor?

Dr. LENFANT. The release of this study has had tremendous impact. And as you pointed out, the companies which are producing aspirin have depicted the result of this study as a panacea. We have seen that through an advertising blast which, as you know, has aroused interest of the Food and Drug Administration and the Federal Trade Commission as well. Since then an agreement has been reached between the aspirin producing companies and these Government organizations, and certainly the advertisement for aspirin has quieted down, so to speak.

The fact is that not everybody, not every male between 35 and 80 years of age should be taking aspirin. To take aspirin because one has a headache, a pain, is one thing, because in this case one would take maybe two or three tablets. But to take aspirin every other day for a long period of time, years, is another question which needs to be addressed and decided upon by physicians.

The study was reported through a rather brief scientific communication in the New England Journal of Medicine. Today the scientific community and physicians would like to review the complete data.

As I mentioned in my opening remarks, the Institute is going to have a 1-day long debate among experts in the field from this country and from abroad to try to come up with a statement as to what individuals indeed should take this treatment.

Now having said that, I would not want to undermine the importance of these results. The fact is that we believe that a very powerful tool has come to us to prevent coronary heart disease. But that tool must be used properly and not necessarily by everybody. What our conference will discuss is who the candidates for this treatment are.

## ASPIRIN STUDY IN PERSPECTIVE

Senator CHILES. Senator Bumpers, did you have questions?

Senator BUMPERS. I just wanted to pursue the aspirin thing just a little bit further. Who did that study?

Dr. LENFANT. That study was done by a group at the Harvard Medical School. The principal investigator was Dr. Hennekens.

Senator BUMPERS. Well, when they talk about an aspirin a day, are they talking about a 500 gram aspirin?

Dr. LENFANT. No; in this particular study my recollection is that it was 135 milligrams every other day.

Senator BUMPERS. Is that about like a baby aspirin?

Dr. LENFANT. Yes; as a matter of fact, that is what it is.

Senator BUMPERS. Well, were they suggesting something of that size every other day? The equivalent of a baby aspirin every day?

Dr. LENFANT. Every other day.

Senator BUMPERS. Every other day.

Dr. LENFANT. Yes; in fact, this is the subject of debates. This particular study had the results, with this particular dose of aspirin. One of the issues is whether the dose is even too high. Some investigators at this time would suggest that perhaps one-half this dose would have the same effect.

Senator BUMPERS. Well, what about arthritis patients who take sometimes a number of aspirin a day for years and years? Were they included in this study?

Dr. LENFANT. No; these were physicians who were basically self-selected, on the basis of their own medical history. This is the problem that we see with this particular study, that it was a very specific group of subjects. Nothing wrong with them, but they were very well informed and educated subjects on the subject matter.

Therefore, to apply the findings to the general population may be a problem, and this is what we want to discuss in a couple of weeks.

### ARTIFICIAL HEART/CIRCULATORY ASSIST RESEARCH

Senator BUMPERS. I see. Now, you have also funded research and development on artificial hearts to try to get away from all the bulky support equipment used with existing artificial hearts.

What is the status of that research, and how promising is it?

Dr. LENFANT. At the present time, the Institute is pursuing several lines of research with regard to the artificial heart.

One is the development of what we call a left ventricular assist device. It is a single ventricle which is activated by electrical power. This research has gone quite a way getting us close to the clinical application.

In fact, the Institute has now under consideration the initiation of a clinical trial to test the efficacy of this device. I would like to underscore that this particular trial is extremely important. Let me take a minute to say why. As you may recall, there have been nine total heart replacements. All of these subjects died for the same reasons: infection, thrombosis, and thromboembolism.

### ASSIST DEVICES AND CLINICAL PROBLEMS

Senator BUMPERS. Infection and thrombosis?

Dr. LENFANT. Yes, sir; the issue that we have today is not whether we can have a mechanically sound device which is going to do the job for a long period of time, but whether the human body can tolerate this device for a long period of time.

We feel very strongly that pursuing development of new devices such as a biventricular device, or one which would be activated by thermal energy, which we are also considering; have a lower priority than answering the question as to whether the human body can tolerate any device for a long period of time.

If the device which is now ready for human application cannot be put into a body, into a person, and if the body reacts to it with thrombosis and infection, our feeling is that there is probably no point in developing other types of devices until we have addressed the question of risk of infection and thrombosis. So we view this clinical trial as being very important.

These comments concern the issue of prolonged ventricular assist or heart replacement, but not the matter of what we call bridge to transplants. This situation occurs when somebody needs to have a heart transplant but there is no donated organ available, if that person cannot stay alive while waiting for a heart to become available, then that person receives a temporary device which will be removed when the transplantation can take place. This is what we call the bridge to transplant.

It has been used in the United States in 170 cases.

### BRIDGE TO HEART TRANSPLANTS

Senator BUMPERS. In 170 cases you have put people on an artificial heart while they were waiting for a heart?

Dr. LENFANT. Yes, sir; yes, sir. And the survival is approximately 44 percent. So it is a technology which has great merit.

But the fact of the matter is that what we would like to achieve is to have a device that can be implanted as a replacement of the natural heart, and left there for a long period of time. But before we do that, we have to answer the question that I mentioned to you earlier.

Senator BUMPERS. How does that survival rate compare with just transplants without the intervention of an artificial heart?

Dr. LENFANT. Heart transplantation today is an extraordinarily successful technology. After 1 year, the survival is approximately 80 to 82 percent, depending on the age. After 5 years, it is I believe 60 percent of 65 percent.

Senator BUMPERS. That is very good. That 44-percent survival rate of those who use an artificial device while waiting, there are other factors involved in that. I guess a lot of those cases have debilitated to the point that they are very difficult anyway.

Dr. LENFANT. This is one point. And the second point is that in these persons as well we have the problems that I mentioned for total replacement, which are the risks of infection and thrombosis. These occur even though the period of being on a device is short.

Senator BUMPERS. Yes.

Dr. LENFANT. This is a really very critical question today.

Senator BUMPERS. Thank you very much. Thank you, Mr. Chairman.

Senator CHILES. Thank you, sir. Dr. Fauci?

## NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Dr. FAUCI. Mr. Chairman, I would like to very briefly summarize my full written statement which I have submitted for the record.

As I mentioned to this committee in previous years, the fundamental theme of the National Institute of Allergy and Infectious Diseases, NIAID, is basic and clinical research on the immune system as an organ system, with the multiple offshoots from this approach.

In that regard, there have been a number of major advances over the past year in understanding, at the molecular level, the basis of the body's defense mechanisms, and how this relates to protecting the body against infectious diseases as well as against the emergence of certain types of tumors.

In addition, understanding of diseases of the immune system—either hypersensitivity or immunodeficiency diseases—has given us a scientific basis to make the many advances that have been made in understanding the pathogenesis or the development of the immune defect associated with the AIDS virus, the human immunodeficiency virus.

In addition, we have come to understand at the molecular level the fundamental causes of asthmatic or allergic reactions, transplantation biology, and a number of other fields.

I came before this committee last year and mentioned a number of activities that were ongoing at NIAID. I would like to update you very briefly on two of these activities that seemed to interest the committee.

Last year at this time we were conducting a trial of an acellular pertussis vaccine in Sweden. By acellular vaccine I mean that it does not contain the entire microorganism, as does the current vaccine that we know is effective in protecting children from pertussis.

But this vaccine from the whole microorganism also produces rare but nonetheless sometimes serious toxic side effects, which have caused a great deal of concern in the United States.

The Swedish trial has been completed in 3,800 children, and we are happy to report that the vaccine has been 80 percent effective in preventing serious disease. Most importantly, there have been no serious toxic side effects.

With that as a background, we are now moving on to expanded studies here in the United States in our own NIH-sponsored vaccine evaluation units. At the same time we are also pursuing the molecular biologic approach to developing an even better vaccine for pertussis.

The area of sexually transmitted diseases is another area that has gained a lot of interest over the past couple of years. I convened a consultant group, an STD study group, of non-Government experts to advise us on how we can upgrade our sexually transmitted disease program.

They made several recommendations which we are implementing. They include the award of more STD research units, with an emphasis on pelvic inflammatory diseases, a major cause of sterility in women, the support of a collaborative study on the relationship of vaginal infections to prematurity in 15,000 women, as well as an increase in behavioral research. All of these are being implemented in our program.

As I mentioned to you when I testified with the Assistant Secretary for Health, there have been a number of major advances in AIDS research—many scientific advances at the basic pathogenesis level, as well as in molecular virology.

AIDS treatment research, as you have heard from Dr. DeVita just a few moments ago, is also proceeding rapidly and with some interesting results. At the present time, there are 35 AIDS clinical trials units throughout the country that are sponsored by NIAID.

Over 3,500 patients have been accrued into clinical trials. At the present time, there are 20 active protocols, 5 of which have completed accrual of patients and there are an additional 15 protocols in the developmental stage.

In that program of clinical trials, a number of antiretroviral, immunomodulator, antiopportunistic infection, and antineoplastic drugs are currently being evaluated.

Finally, with regard to AIDS vaccine development, the vaccine trials that are supported by the NIH, both intramurally here on the Bethesda campus, as well as in our vaccine evaluation units, are phase 1 trials looking at the safety of administering a recombinant DNA protein of the AIDS virus. The protein, GP–160 is a compound of the outer coating of the envelope. Those trials are proceeding along quite well, and there have been no serious toxic side effects.

We are asking the committee for an appropriation of $435,084,000 for non-AIDS. Our share of the Assistant Secretary's AIDS money is $310,268,000.

This concludes my oral statement, Mr. Chairman. I would be happy to answer any questions you might have.

## REARRANGEMENT OF GENES

Senator CHILES. Tell me a little bit more about Dr. Tonegawa's findings.

Dr. FAUCI. Yes; indeed. Dr. Susumu Tonegawa is a researcher from the Massachusetts Institute of Technology who is a grantee of the Allergy and Infectious Diseases Institute as well as other NIH Institutes.

Over several years he has pioneered research in trying to understand how the body, which has a limited number of genes that are responsible for coding proteins that can recognize a number of stimuli to which the body is exposed, can respond to virtually an infinite number of stimuli.

In other words, how can you make millions and millions of antibodies with different specificity when you have a limited number of genes?

His fundamental discovery is that the genes rearrange themselves so that although the genes are limited in number, through rearrangements of genes when they are coding for these antibody proteins, we can have an almost unlimited capability.

It is one of the major seminal observations in understanding how the body can protect itself against millions of different types of organisms.

Senator CHILES. That opens the door for a lot of change.

Dr. FAUCI. I think that is a very good example, Mr. Chairman, of what I meant in my lead statement about understanding the basic mechanisms of the immune system producing offshoots in so many different disciplines—not only in disciplines of immunology but in a number of crosscutting areas.

The observations that was pioneered by Dr. Tonegawa has allowed us to be able to understand how we react to microorganisms. It allowed us to have a better insight into vaccine development, into transplantation biology, into understanding how the body responds to a variety of stimuli and other mechanisms of hypersensitivity diseases. It has enormous implications—a very well-deserved Nobel Prize.

Senator CHILES. So there will be a lot of offshoots from this discovery now and a lot of people will be benefiting from that.

### AIDS—INCREASE IN FUNDING AND FTE'S

Senator CHILES. We notice that there is a mismatch in regard to the AIDS personnel compared to the growth of AIDS funding. What kind of problems is that causing?

Dr. FAUCI. At the present time, as you know, there has been an extreme growth in the amount of funding for AIDS research. In 1982, the NIH had $3 million and now the request is for $587 million. The amount for our own Institute is for $310 million.

Eighteen new FTE's are included in the NIAID request. We are doing quite well with what we have. There is still a disproportionate increase in the amount of funding versus the FTE that can effectively manage those funds.

Senator CHILES. Well, do you have enough personnel in the AIDS program to meet our 6 months directive of getting all the grants done?

Dr. FAUCI. Our 1989 current estimate for the Institutes, as well as the clinical center, is 580.

By 1989 we would need an increase of 375, by 1990 188, and by 1991 an additional 168. So there is an incremental requirement this year and over the next few years.

Senator CHILES. I note the President's AIDS commission recommended the number of personnel involved in drug trials be increased from 47 to 120. Is that your highest area of priority for personnel?

Dr. FAUCI. That is a high priority area. There are a number of other areas that are also of high priority. Being able to administer the very complex clinical trials of drugs is very important. But I must also say that there are other areas that also have high priority.

### FUNDING FOR AIDS RESEARCH FACILITIES

Senator CHILES. Last year the Congress provided $19.2 million to expand AIDS-related facilities at NIH. I note the administration's request is for $5 million for routine repairs and maintenance.

Are there any AIDS-related facility requirements that you have become aware of since your budget was submitted?

Dr. FAUCI. Since the $19 million—no, those $19.15 million are now being implemented.

Senator CHILES. Well, this year you are talking about $5 million. I am asking for routine repairs and maintenance. Do you have any requests since that time?

Dr. DEVITA. Well, there is a slight shortfall. In one of the projects that was established with the moneys that were provided would buy about $900,000, to be accurate.

Senator CHILES. Well, my understanding is that Congressman Waxman on the House side has asked the question like this and had a number that was something to the extent of $48 million that needed additional facilities.

I want to know, I want the same kind of answers or find out whether it is—last year I sort of asked this question, I think, and I was told that we had covered it.

Somehow between our hearings and the time we got to the floor there was a development for additional need for facilities. And then it was placed on the floor. I at least want to know what the heck the need is. Before we get to the floor.

Dr. FAUCI. I am not sure what $48 million you are referring to.

Dr. WYNGAARDEN. I am not certain either, Senator Chiles.

Senator CHILES. Well, I would like somebody to check that.

Dr. WYNGAARDEN. Yes; we will do that.

### AIDS—ADDITIONAL FUNDING REQUIREMENTS

Senator CHILES. The AIDS request for 1989 is $223.4 million, up $86 million or 39 percent above 1988. That is based on your submission to OMB last summer.

Are there additional requirements that you are aware of that have come up since your original budget submission?

Dr. FAUCI. As I have told the committee before, when we put forth our proposed needs for clinical trials in AIDS, they were projected based on a certain number of agents that might enter from a phase 1 to a phase 2 trial.

When we went to our grantees to ask them what their needs would be for the coming year, there had been so much acceleration and progress over the past year in clinical trials of certain AIDS drugs that they came in individually with requests that were greater than what would be covered by the appropriation.

We are currently in the process of evaluating them on an institution-by-institution basis to see if we could meet those commitments, or if, in fact, we need to get more money into that particular clinical trial.

Senator CHILES. When will you have a decision on that?

Dr. FAUCI. It would be very soon. We are in the process right now. We have people out in the field with them. So I would imagine that that would be within the next week or two.

Senator CHILES. Well, we would like to be informed.

Dr. FAUCI. Yes; we will do that, Mr. Chairman.

### COMMON COLD

Senator CHILES. Dr. Fauci, you are well known as the Director who supervises most of the AIDS research. Many of us have sort of forgotten that your Institute is also responsible for research on the common cold. Have you got a cure for that yet?

Dr. FAUCI. I am sorry to report to the committee, Mr. Chairman, that we do not have a cure for the common cold.

The kinds of research that I was talking about, the basic research in understanding at the molecular level the variability, not only among functions of cells but also in the structural components of microorganisms, has shown us that the common cold is not caused by a single agent. It is caused by a group of agents that probably have 100 different types among them. The cold viruses are called rhinoviruses.

Current research involves applying the techniques of molecular biology and structural biology to determine what the common structural components of these very many different groups of viruses are. Then one could direct a particular type of antiviral therapy to block, for example, the binding of the rhinovirus to its target tissue in the upper airways the nose or the pharynx.

It is exactly this kind of basic research that we were talking about a little while ago in the discussion on AIDS in which we mount a major structural biological effort in understanding viral structure, which will have a number of offshoots.

### GORGAS INSTITUTE

Senator CHILES. Dr. Fauci, your Institute has a division which focuses on tropical diseases. The Fogarty International Center at NIH funds the Gorgas Tropical Disease Institute in Panama.

To what extent do you rely on the research work done by the Gorgas Institute? And do you believe we could recompete the Gorgas Institute research work or have it handled by your Institute?

Dr. FAUCI. Well, I think that is something that can be considered. Right now the Gorgas Institute is not part of our Institute but could presumably apply to us for support through a standard funding mechanism.

For example, we issued a request for applications for international collaboration in AIDS research, which we call ICAR. It is modeled after our international collaboration in infectious diseases research program which supports collaborative research between institutions in the United States and institutions in foreign countries that have a special interest in tropical medicine.

Specifically in this case the program deals with AIDS. The applications in response to the RFA are in the process of being peer reviewed.

I think that if there is a situation where we can collaborate with the Gorgas, it deserves consideration.

Senator CHILES. I need to take about a 5 minute break at this time.

[A brief recess was taken.]

Senator CHILES. Dr. Löe?

### NATIONAL INSTITUTE OF DENTAL RESEARCH

Dr. LÖE. Thank you, Mr. Chairman. As you correctly noted during your introductory remarks, on June 24, 1988, the NIDR will celebrate its 40th anniversary. I believe it is no exaggeration to say that 40 years of federally supported dental research have changed the face of America. And decidedly to the better.

Senator CHILES. We are longer in the tooth now.

Dr. LÖE. Pardon?

Senator CHILES. We are longer in the tooth now.

Dr. LÖE. That is right. Next month NIDR will announce results of a recent national children's survey, similar to the one that we conducted in 1979. Preliminary analyses indicate that the declines in tooth decay reported in earlier surveys are continuing, and that today close to 50 percent of children in America 17 years and under have never had a cavity; never had a filling.

Last year I reported on significant improvements in the oral health of working adults. However, Americans over 65 are not faring well. Forty-two percent of the seniors are toothless, and those who have teeth have more tooth decay and periodontal diseases than their counterparts below 65.

The NIDR has set its sights on identifying all individuals, young and old, who are at high risk for oral diseases. We want to eliminate toothlessness in this country and improve the oral health of all Americans.

Our plan is to expand research and collaborative activities to create an oral health promotion program for the Nation using the latest cell and molecular biology techniques to develop better means of diagnosis and better means of prevention of oral diseases. In addition, we are now reviewing applications for research centers targeted to research on oral health in aging.

In AIDS research, we have documented several changes in salivary components that may appear early in the natural history of this disease. At the same time our researchers have preliminary evidence that the saliva of healthy individuals contains a factor that can prevent the AIDS virus from infecting cells—further corroborating evidence that AIDS is not likely to be transmitted through saliva.

Finally, I would like to report that NIDR scientists have developed some exciting new classes of drugs that, at least in laboratory animals, can prevent the spread of cancer.

Mr. Chairman, in 40 years, to go from water fluoridation and the prevention of tooth decay, to the potential control of cancer metastasis, is good progress.

I look forward to the next 40 years, confident that the increased depth and the extended reach of dental research can move dentistry further along and continue to improve the oral health of all Americans.

Mr. Chairman, the fiscal year 1989 budget request for the National Institute of Dental Research is $127,157,000. In addition to that, the AIDS budget amounts to $3,526,000.

I would be pleased to answer any questions that you may have.

## CHEMICAL MODIFIED TETRACYCLINE

Senator CHILES. Thank you, sir. Tell me a little bit more about your CMT, how that is used.

Dr. LÖE. CMT is an acronym for chemically modified tetracycline. A few years ago it was discovered that tetracycline had a major impact——

Senator CHILES. Tetracycline was a common antibiotic that——

Dr. LÖE. It is a common broad spectrum antibiotic. Now, it turned out that tetracycline had a major impact on periodontal diseases, and also on some other chronic inflammatory conditions found elsewhere in the body.

The mechanism of action of tetracycline was twofold. Not only did the drug have an antibacterial effect, but it also seemed to affect enzyme production in inflammatory cells. Specifically, tetracycline prevented the production of collagenase, the enzyme responsible for the breakdown of connective tissue in skin, in the mouth, and in bone, indeed, wherever connective tissue is found. Further research along this line also confirmed that this property had a major impact on the development of arthritis. So the next step in this research was to try to eliminate the antibacterial component of the drug. This was achieved; so we are left with a molecule that is very close to tetracycline but does not have the antibiotic effect.

Tests have shown that the new compound, CMT, inhibits collagenase production, and thus can have a major impact on the development and the prevention of chronic inflammation.

This drug should soon be ready for clinical testing in patients with periodontal diseases and arthritis.

## GERIATRIC ORAL HEALTH CENTERS

Senator CHILES. The national survey of adult dental health, which was released last spring, showed a dramatic drop in the rate of tooth decay over the previous decade.

You pointed out in your statement that the elderly suffer the worst of any age group; they have the worst oral health and have problems retaining their full number of teeth.

To address those problems with the elderly, the committee provided $500,000 to begin planning efforts for establishing three geriatric oral health centers, for clinical trials, training, and research activity. We also asked NIH to begin planning for additional therapeutic centers.

In spite of these directions, the National Institute of Dental Research budget shows 16 centers in 1988 and 16 in 1989. Tell us what progress is being made in establishing these centers.

Dr. LÖE. A request for applications for research centers on oral health in aging was issued last fall, and we have 14 applications in hand at the moment. We are staging an expedited review so that by the middle of July we will have a second review of the applications, and expect to fund up to four centers on oral health in aging before the end of this fiscal year.

### SMOKELESS TOBACCO RESEARCH AND EDUCATION

Senator CHILES. What programs does the Institute have underway to warn the American public of the dangers of using chewing tobacco?

Dr. LÖE. Using——

Senator CHILES. Chewing tobacco.

Dr. LÖE. First of all, we are trying to get a handle on how big this problem is. It turns out, both when it comes to chewing tobacco——

Senator CHILES. I will include snuff.

Dr. LÖE. Yes; smokeless tobacco is the general term. We have found that there are high numbers of college students who are using snuff. And there are athletes who use all sorts of smokeless tobacco. There are also older people who use smokeless tobacco to a substantial degree.

Senator CHILES. We notice there are always tremendously attractive advertising campaigns that use leading athletes and others to promote the product.

Dr. LÖE. All these smokeless tobacco brands cause changes in the mucosal lining of the mouth, and cause precancerous lesions and cancer.

So we have asked for more attention to the problem from the research community. We have quite recently funded a program project grant at the University of California at San Francisco. They have conducted a pilot study of major league baseball players on the west coast and are now developing a full-fledged protocol to broaden the study.

The protocol includes a characterization of oral lesions associated with smokeless tobacco use, how frequently they occur, and what happens to the lesions following the termination of the use of smokeless tobacco. So a major study is underway there.

Senator CHILES. When will they be publishing results from that study?

Dr. LÖE. This is a 5-year study, so we expect to have more definitive information on this topic some time in the 1990's.

### DENTAL FEAR AND ANXIETY

Senator CHILES. A sizable portion of the public avoids regular visits to the dentist because of anxiety regarding pain.

The National Institute of Dental Research spends approximately $5.8 million on behavioral research focused on this subject each year, and approximately $0.5 million in outreach or educational efforts focused on overcoming this anxiety.

I understand that you expect to spend $5.8 million in 1989, again focused on anxiety regarding pain. What have you learned from the research and what additionally do we expect to learn?

Dr. LÖE. First of all, I would like you to know, Mr. Chairman, that the percentage of the population that is seeing the dentist for checkups is increasing. During the adult survey that we completed in 1987, we collected data on the frequency of dental visits. It turns out that approximately 80 percent of the population of employed adults is seeing the dentist on a regular basis. This is an enormous increase in the course of the last 10 or 15 years.

Now, it is true, that a substantial segment of the population is frightened of seeing the dentist. This is, of course, a misperception; because seeing the dentist today is essentially a painless experience. We have come a long way in pain control and also in developing other approaches to the procedures of restorative dentistry and surgical intervention. So the fear problem is probably not realistic in terms of what goes on in dental offices today.

We have supported a number of research projects focusing on ways to alleviate dental fear and anxiety. And they have been very successful—especially among children—who seem to be very responsive to environmental approaches to the relief of anxiety and fear.

We expect that as we continue to mount these efforts we will see continued reductions in the problem of dental fear. We don't expect to reach 100 percent, but I am sure that we are going to make major inroads in this area.

Senator CHILES. Thank you. Dr. Williams?

## NATIONAL INSTITUTE ON AGING

Dr. WILLIAMS. Thank you, Senator Chiles. I would like to give a few highlights of the National Institute on Aging's efforts to accomplish what you well stated yesterday as a goal. Namely, to add real life to the last years of life.

Alzheimer's disease, one of the principal threats to this goal, is a major and very costly epidemic in our Nation, currently affecting between 2½ and 3 million older persons.

Within the last year the research efforts of our Institute and other Institutes have produced a number of very exciting advances, and I will cite just a couple of them.

It has been found that nerve growth factors can stimulate the growth of nerve cells in the brains of animals, including specifically cells of the types which are mainly lost in Alzheimer's disease. There is the real prospect when certain hurdles are crossed that nerve growth factors may be useful and effective in restoring or improving nerve cell functions in those afflicted with this disease.

Another very exciting recent finding is that Alzheimer-like lesions have been produced in cell cultures from skin biopsies of Alzheimer victims, but not in similar cultures of skin cells from normal subjects. This holds the promise for more accurate diagnosis in living patients and opportunities for understanding the disease process.

We are also proceeding with the clinical trial of THA through our 10 Alzheimer's disease research centers and in 7 other settings.

Also this year, as Congress has directed, we have developed plans for an Alzheimer's disease education center to disseminate the latest accurate information on this condition, including diagnostic treatment and care aspects, to the public and family members, as well as professionals.

In other research arenas, molecular biological techniques are proving very valuable in addressing the basic characteristics of aging, including identifying the genetic origins of so-called senescent proteins which suppress the proliferation or growth of cells in older cell cultures, and may have a relationship to suppressing cancer proliferation as referred to by Dr. DeVita earlier.

Providing resource support for aging research is a sustained commitment of our Institute. Such resources, without which much of the aging research would not be possible, include cell banks for use of scientists around the country, provision of rodents for animal research, and epidemiologic data bases for very old persons.

In particular, in relation to epidemiologic studies, we see particularly promising opportunities for comparative international crosscultural studies on dementia, osteoparosis, and other common problems. These studies will be carried out jointly with assistance from the Agency for International Development and the World Health Organization's special program on research in aging, which has just been established and based with the National Institute on Aging.

But perhaps our most important concern about resource development is the training and career development of future investigators and academic leaders in these fields. In addition to continuing our already ongoing efforts, and consistent with recommendations of an Institute of Medicine study in the past year, we are proceeding with initial plans for centers of excellence for research and training in geriatrics.

These are a few highlights, Mr. Chairman. Our budget request is for $204,770,000, with an additional $452,000 requested for AIDS. I will be glad to take questions.

Senator CHILES. Last year the 1987 supplemental, in the supplemental the subcommittee provided the startup funding for the clinical trials of THA.

I see that with interruption in the research now it is going on. From the THA trials to date, in view of the criticisms that have been leveled at the underlying research, is it worth continuing?

Dr. WILLIAMS. Yes, sir; I think there is no question in my judgment, or that of the entire scientific community in this field, that it is essential to continue this study.

The initial findings which were reported in a reputable medical journal, although they were on a few subjects, were certainly suggestive that patients respond to this drug. And the rationale for the drug is sound.

Its effect is consistent with what one might hope would happen in Alzheimer victims, but there were no data on toxic effects in the initial report. And as I stated, a very small number of subjects were tested in that first report.

Soon after that report came out, we convened an outstanding panel of experts to advise us. Their unanimous advice was that we should undertake a careful clinical trial of this drug. We have proceeded through the regular peer review mechanisms to receive and award support.

While we did find initial toxic effects on the liver in terms of liver chemistry changes, the trial is going well now.

Senator CHILES. Well, I understand if it proves successful it is just going to slow the deterioration of memory loss in Alzheimer's patients.

Dr. WILLIAMS. Probably so. What we would expect would be a delay in the decline of memory function and other cognitive functions and possibly adding 1 or 2 years to the effective life period. But that is quite a valuable thing, even if that is the most we could achieve.

Senator CHILES. What Alzheimer's research and what percentage of the total is focused on actually understanding the degeneration of brain cells that cause Alzheimer's disease?

What prospects do we have for a better understanding and curing the disease?

Dr. WILLIAMS. The area of understanding the basic causes and mechanisms of the disease is by far the major part of our support.

Overall, our Institute is investing about $55 million in fiscal year 1988 in Alzheimer's research, and at least 80 percent of that is going into basic studies on the causes of Alzheimer's, including some work on early diagnosis.

That applies also to research supported by the National Institute of Neurological and Communicative Disorders and Stroke, the National Institute of Mental Health, and two or three other Institutes that have smaller investments.

Senator CHILES. Well, we are seeing a great, or a rising number of cases predicted for Alzheimer's disease.

We have asked this question earlier about whether that is a result of the growing incidence, is that a result of the increasing population, is that a result of better diagnosis, that we are able to discover more?

What is your answer to that? And we are seeing numbers by some Alzheimer's institutes that have the number of cases up to 4 million by the year 2000.

Dr. WILLIAMS. That there has been no evidence of an increasing rate of occurrence of this disease, but rather that we have been diagnosing Alzheimer's more correctly. And we are also confronted with the growing numbers of older people. We will have a doubling of the population over the age of 85 between now and the year 2000. It is in this very old age group that the prevalence of Alzheimer's disease reaches something on the order of 30 to 40 percent of the population over the age of 85.

Therefore, it is a combination of more adequate diagnosis and the rapid growth of very old people. It is still worth noting that at least 50 or 60 percent of very old people do not have dementia.

Senator CHILES. Well, I have noted or heard before that it is almost an autopsy many times to know whether you really had the disease which you are dealing with or not.

How soon are we going to have something that will tell us quickly or predict it?

Dr. WILLIAMS. The NIA sponsored a consensus development conference this past year to bring together the evidence about differential diagnosis of dementia, and it was quite successful.

Using the current guidelines for careful workup, the diagnostic accuracy is about 90 percent when compared ultimately with the postmortem findings. But to be entirely precise, we need an objective measure that can be applied through tests of blood or cerebral spinal fluid. Another potential test is the skin culture technique that I referred to earlier, where skin cells from Alzheimer's victims show changes in a certain culture media similar to those seen in the brain tissue while normal skin culture cells do not.

If this test is borne out with more quantitative data, it would be essentially an absolute way of seeing the actual pathologic change from a skin biopsy.

There is good evidence that we will have measures from the spinal fluid and possibly blood that will show certain abnormal proteins which have already been identified as being rather specific in Alzheimer's disease. It simply needs more confirmation. We have several opportunities to have an objective diagnostic test.

Senator CHILES. The number of Americans over 85 years of age is expected to double in the next 15 years. We have got 37,000 pediatricians, 45,000 veterinarians, and about 200 trained and qualified doctors specializing in old people.

By the year 1990 the Nation is going to need some 10,000 of these people for teaching, treating, and research. What is the Institute of Aging and NIH have to help increase the supply?

Dr. WILLIAMS. I have considered this one of the highest priorities for the NIA since I have been director and have done everything possible to expand our efforts in training and career development for academic leadership.

We need teachers and investigators first in order to give leadership to training larger numbers of physicians in this field, and we have made progress. We are now proposing to move on to centers of excellence for research and training in geriatrics, analogous to research and training centers that exist in such fields as diabetes, arthritis, and cancer. I believe this will be another boost forward in our training initiative.

As an indication of the progress we have made; last week the first examination for special competence in geriatrics was conducted jointly by the American Board of Internal Medicine and the American Academy of Family Physicians. Approximately 4,000 physicians took this examination, showing a widespread interest in becoming recognized as having some special competence in geriatrics.

While these are primarily practitioners, some will be clinical teachers as well. This is a laudable step forward. But our primary effort is to generate teachers and researchers in the field of geriatrics and gerontology.

Senator CHILES. Well, it is going to be very important that we do that, I think. Dr. Kupfer?

## NATIONAL EYE INSTITUTE

Dr. KUPFER. Mr. Chairman, the National Eye Institute supports a broad range of clinical and laboratory research, which has an impact not only on problems of prevention of blindness and of visual disability, but also impinges on other clinical conditions.

Perhaps the first example I should give where researchers supported by the National Eye Institute have made a major contribution in understanding the mechanisms of cancer, concerns the malignant tumor of the eye called retinoblastoma. Last year, we reported that the genetic basis for this disease had been defined, and this year the gene has actually been isolated and cloned. This is the first human cancer gene or oncogene to have been isolated and cloned. An interesting aspect of this disease is that it occurs only when the gene is absent, which is exactly the reverse of the usual oncogene activity that we are more familiar with.

In the clinical arena, just in the last month, we announced the very favorable results of a clinical trial evaluating treatment for the disease called retinopathy of prematurity. This is a disease that annually affects about 2,600 very low birth weight premature infants. The very simple instrument that I am demonstrating here, which is connected to a refrigerant, that lowers the temperature of the tip to minus 60 to minus 80 °F is applied to the outside of the premature infant's eye, adjacent to the retina. This stops the proliferation of blood vessels that grow rampant in premature infants, and reduces by 50 percent the number of infants that develop complications that usually lead to blindness.

These are just two examples of advances in vision research, one from basic laboratory research looking at disease mechanisms, and one clinically applied clinical investigating treatment of a blinding disease of children.

The NEI's request for fiscal year 1989 is $229,021,000. I would be happy to answer any questions, sir.

### LOW VISION AIDS

Senator CHILES. Advances in video cameras and computers are making it possible for people with limited vision to read, write, and work independently. Much of that research was initially developed by NASA in its space program.

Could you describe for the committee the technology and the progress being made for high-tech devices to help those with limited vision?

Dr. KUPFER. We have been very interested in supporting research to improve the residual vision in patients with visual disability. There have been a number of approaches, either directed toward helping such individuals read or ambulate.

Reading devices have been developed in two directions. One has involved magnification of a page of a book, and the other the scanning of a book or a letter that converts the words into a simulated voice so that one can hear what is on a page of print. Such scanning has reached a very high level of sophistication.

There have been attempts to utilize, as you mention, Mr. Chairman, the technology of NASA that uses a variety of devices to capture an image and then translate that image into a high-resolution picture that could be used to help people with low vision to ambulate.

Such a collaborative study is now underway between Johns Hopkins Wilmer Eye Institute and NASA. In fact, they are having a press conference this morning, which one of my staff is attending. The NEI has been instrumental in supporting the low vision research activities of the Wilmer Eye Institute.

Senator CHILES. What is the nature of their press conference? What are they announcing?

Dr. KUPFER. They are announcing the collaboration of NASA and Johns Hopkins to develop a prototype of a small TV camera that could be mounted in a pair of glasses and scan the environment as an individual with low vision attempted to ambulate. Such a device would create an image that could be visualized by that individual.

In other words, it would provide major magnification with attention to the important details, such as curbs, corridors, doors, and walls. This is a very important advance in involving appropriate engineering talent in the development of low vision aids.

Through the use of small business grants, we have been able to encourage engineering companies and individuals knowledgable about optics to develop much better low vision aids. These have been improved not only in terms of the quality of the optics but, what is also very important, the cosmetic appearance of such aids. These are being actively developed.

Senator CHILES. What is the progress on the scanner for the book that you mentioned, the talking book?

Dr. KUPFER. It is commercially available now, and at a very high degree of development. The voice simulation it provides is quite good, and its accuracy in scanning printed material is excellent. They are now trying to develop scanners that will scan handwritten letters.

Senator CHILES. Scan what now?

Dr. KUPFER. Handwriting, rather than typed or typeset material.

## CATARACTS

Senator CHILES. Cataracts are the most common cause of impaired vision, as well as the third leading cause of blindness. It is estimated we spend about $1.4 billion on cataract surgery each year.

The Institute currently has underway a clinical trial to determine whether or not aspirin taken on alternative days reduces the risk of developing cataracts between men in the United States between 40 and 84.

Are there any preliminary results from this clinical trial?

Dr. KUPFER. This actually is the same study that Dr. Lenfant addressed.

We added this cataract-related component to the study of physicians who are receiving either an aspirin or a placebo every other day. These physicians will be asked whether they have developed cataract during the study period of 2 or 3 years. Because this is a knowledgable group, they should be able to report accurately.

We hope to have results from this study in the next 6 months.

### GLAUCOMA

Senator CHILES. Glaucoma is the No. 1 cause of blindness in blacks, and six times more prevalent in blacks than in whites.

Is this higher incidence level for blacks true in other countries around the world? Is there any known risk factor other than a family history of glaucoma?

Dr. KUPFER. We have completed a pilot study in Barbados, West Indies, where the ancestry of population is mainly from what is now known as Ghana in West Africa.

The prevalence of glaucoma in blacks aged 53 and above is somewhere in the range of 12 percent. This is eight or nine times higher than it would be in a comparable white population.

We are also supporting a study in Baltimore in which there is a direct comparison between glaucoma in whites and blacks. Again the very high prevalence in blacks is being supported.

A third study has been done in St. Lucia in the Caribbean, and that again has indicated the prevalence of about 13 percent. So there does seem to be a very high prevalence of glaucoma, open angle glaucoma in blacks worldwide.

Now, what the cause is we do not know. But we are doing studies, especially in Barbados and in Baltimore, to try to identify the risk factors that make this population so highly susceptible to the damaging effects of increased pressure.

Senator CHILES. Well, are there—I noticed we provided $1 million for 10 new physicians for expanded education, a campaign targeted on early detection.

Are we doing enough there? And should we be making special efforts for the black population given the fact that they are so much more at risk?

Dr. KUPFER. Yes, sir; as a matter of fact, on the basis of that funding of $1.1 million, the National Eye Health Education Program has begun.

This coming Saturday there will be the first meeting to which experts in glaucoma, health services research, experts also in diabetes because again I think the message has got to go out in diabetes.

People from the private sector, from the nongovernmental organizations sector, as well as from NIH. We want to tap into the expertise of some of the other Institutes at NIH that have had experience in disseminating health information.

The purpose of this organizational meeting will be to prepare an agenda for a major conference to be held in the fall at which time we will define and develop priorities and strategies relating to eye health education and establish what the needs are in this area for both glaucoma and diabetic retinopathy.

There is no doubt that the black population will be a major target population in this program.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. There are several questions for each of the Institute's that members of the subcommittee have and they will be submitted to you for your response.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## CYSTIC FIBROSIS CENTERS

Question. Last year, the Committee directed that you fund various Cystic Fibrosis Centers. How many have you funded to date?

Answer. Because the applications for cystic fibrosis centers are being reviewed, we have not funded any cystic fibrosis centers to date.

Question. How many do you plan to fund?

Answer. We plan to fund one center beginning in September 1988. In addition, the National Institute of Diabetes and Digestive and Kidney Diseases plans to fund 2 or 3 cystic fibrosis centers.

Question. What are your plans for expansion in FY 89?

Answer. The FY 89 budget request does not propose a further expansion of this program.

## CARDIAC ENERGETICS PROGRAM

Question. Dr. Lenfant, in your request you describe a new intramural program of "cardiac energetics." Would you describe this new program and tell us how much money will be committed to this activity in 1988 and 1989?

Answer. The Institute established the Laboratory of Cardiac Energetics in FY 1988. This new program involves research on the evaluation of energy utilization of cardiac muscle in living systems. This program utilizes and develops state-of-the-art, noninvasive techniques involving magnetic resonance imaging (MRI) optical spectroscopy for the study of cardiac biochemistry and function.

The information gained from using MRI has and will provide fundamental insights into the regulation of cardiac performance under normal and pathologic conditions. While most of the studies in this program have been limited to animal models, clinical investigations are being planned. The direct application of these noninvasive techniques to man will permit further investigation of human heart physiology and lead to improved diagnosis and treatment of heart disease. The Institute plans to obligate approximately $550,000 for this program in FY 88. The level for FY 89 has not yet been determined.

Question. What do you see as the potential benefits of the program on cardiac energetics?

Answer. The potential benefits from this program are extremely important. First, the information concerning heart metabolism, that is, how raw materials or nutrients delivered to the heart cells are converted into the pumping action of the heart will be used to guide the development of new strategies in the prevention and treatment of heart disease. Second, the techniques developed in this program will eliminate many of the invasive diagnostic procedures used to evaluate heart function such as cardiac catheterization and coronary angiography. In addition, these techniques will permit the analysis of cardiac anatomy and function without the use of harmful ionizing radiation such as x-rays and radioisotope tracers. Finally, these new approaches to the study of cardiac energetics may provide noninvasive diagnostic procedures of the heart that could improve the detection and characterization of early heart disease and high risk populations.

Question. The cardiac energetics program appears to have great potential for advancing heart research. Do you foresee any special problems in marshalling the resources to fully implement this program?

Answer. A research team working on the use of MRI for the study of the cardiac energetics is present in the intramural program and will serve as the central catalyst of this program. This group, consisting of physiologists, chemists and physicians, has demonstrated the ability to adapt this rather complicated technology to the study of the heart. In addition, this program has been successful in evaluating many issues of cardiac energetics using MRI and the laboratory is an acknowledged world leader in this field.

To initiate human studies it will be necessary to acquire a new, state-of-the-art MRI instrument which is expected to cost approximately $4.5 million. An additional $250 to $300 thousand is required to do the necessary renovations and construction for installation. Funding the purchase of a single item of this magnitude is a problem that has not been totally resolved.

## PULMONARY SURFACTANT

Question. Has there been recent progress in the development of surfactant replacement therapies for treatment of respiratory distress syndrome of the newborn?

Answer. The Institute continues to support basic research and clinical studies that seek to elucidate the role of surfactant replacement in treatment of respiratory distress syndrome (RDS) of the newborn, a condition that affects approximately 40,000 babies per year in the U. S. Neonatal RDS occurs most frequently in premature infants. It is characterized by a deficiency of pulmonary surfactant, a complex material that is made by certain cells found in the alveolar region of the lung. The surfactant functions to prevent lung collapse and is essential for normal breathing. Ever since the discovery that the lung surfactant is deficient in babies with neonatal RDS, pulmonary researchers and neonatologists have worked towards the goal of developing a therapy to replace the surfactant in these babies. Several different types of surfactants are being tested in research laboratories and in clinical trials throughout the U. S. and Europe. Some of the surfactant preparations are derived from animal lungs, others are synthesized completely in the laboratory, still others have been produced through recombinant technologies.

Results from several small clinical studies are encouraging, and suggest that surfactant replacement therapy provides immediate benefits in pulmonary function. New studies performed this year suggest that multiple doses of surfactant given to babies as early as possible after birth produce a sustained positive response and improved survival. The babies given surfactant are being carefully monitored for any adverse effects of the treatment. It is likely to be a few more years before a surfactant preparation becomes widely available for treatment or prevention of neonatal RDS.

Question. Could surfactant replacement be used to treat adult lung disorders?

Answer. Although adult respiratory distress syndrome is quite different in etiology from the syndrome that affects newborns, a deficiency or abnormality in surfactant may play a role. The potential uses for surfactant in treatment of other pulmonary disorders including pneumonia and prevention of oxidant injury are starting to be explored. Whether the surfactant, which has remarkable spreading properties, will aid in delivery of drugs to peripheral regions of the lungs is not yet known. Clearly, surfactant research has been driven by the desire to eradicate RDS in newborns, yet it promises to yield exciting progress in the treatment of adult lung diseases as well.

## SPECIALIZED CENTERS OF RESEARCH
## SLEEP DISORDERS

Question. We asked that the NHLBI implement a new Specialized Centers of Research (SCOR) program in cardiopulmonary disorders during sleep. What is the current status of this program and how is it expected to enhance efforts in this area of pulmonary research?

Answer. The new Specialized Centers of Research (SCOR) program in Cardiopulmonary Disorders of Sleep will be implemented by the end of FY 1988. The NHLBI currently supports only a small number of research projects that combine both basic and clinical studies on cardiopulmonary disorders during sleep, and it is expected that this new program will enhance research efforts in this area.

The objective of this new SCOR program is to stimulate a multidisciplinary approach that will integrate basic sleep research, as it relates to the heart and lungs, with clinical studies of cardiopulmonary sleep disorders. Basic studies could address the pathophysiology of sleep disordered cardiopulmonary function, the anatomical and functional involvement of the upper airway, animal models of sleep apnea, fundamental neurophysiological and neuropharmacological aspects of the central nervous system during sleep, and application of molecular biological studies to cardiopulmonary disorders of sleep. Clinical investigations could focus on the etiologies, natural history, prevention, and diagnosis of cardiopulmonary disorders associated with sleep, and the development of new interventions to prevent or ameliorate this disorder.

A multidisciplinary approach to understanding cardiopulmonary function during sleep, fostered through the SCOR mechanism, may unravel the sequence of events that produce the potentially life threatening sleep apnea syndrome, and possibly lead to better modes of therapy. This approach will assure that advances in basic sciences are rapidly translated into effective clinical procedures.

## CYSTIC FIBROSIS

Question. Much success has been reported in recent years in our understanding of many genetic diseases. What is the current status of progress in cystic fibrosis?

Answer. Progress continues to be made toward the understanding of cystic fibrosis (CF), the most common lethal genetic disease among white Americans. The localization of the CF gene to the long arm of chromosome 7, reported last year, has been followed by the isolation of smaller DNA segments containing the defective gene and attempts are underway to characterize it. Once the CF gene is isolated and cloned, it should be possible to define the gene product and identify the physiologic locus perturbed by it. The basic defect in cystic fibrosis relates to an apparent inability of the cells lining the airway surfaces to facilitate the normal transport of sodium and chloride ions, resulting in an increased absorption of sodium and decreased secretion of chloride. This phenomenon causes the salty sweat, dehydration of airway surface fluids, thickening of the mucus, and impairment of lung defense mechanisms, characteristic of cystic fibrosis. Scientists are beginning to suspect that the product of the CF gene may be a protein involved in the regulation of chloride ion transport. In the near future one may see the convergence of electrophysiologic and molecular genetic findings resulting in a precise definition of the role of the aberrant gene product in causing the electrolyte abnormality in CF.

Another area of gratifying progress is the potential development of candidate drugs which either decrease sodium absorption or increase chloride secretion. Amiloride, a diuretic, has shown some promise in increasing the volume of airway surface liquid without evidence of toxicity. The effectiveness of this drug in correcting the electrophysiologic dysfunction in CF is currently being investigated in a clinical study.

Question. What is your Institute doing to hasten this progress?

Answer. The National Heart, Lung, and Blood Institute is continuing to promote various avenues of research to hasten this ongoing progress. Further basic studies on the ion transporting elements in CF cells are being encouraged. A program aimed at developing CF cell lines with indefinite life span--immortalized cells--to provide a steady supply of cells for cellular and molecular studies on the basic defect in CF will be implemented during this year. A national competition for awards to establish multidisciplinary cystic fibrosis research centers has been initiated. Another planned program has the goal of developing and evaluating educational programs designed to assist CF patients and families to participate in rigorous treatment regimens and cope with the psychosocial complications of this disease.

With the potential for isolation of the CF gene on the horizon, gene replacement becomes a distant but alluring preventive approach for CF. In the meantime, the Institute will continue to direct its programs towards further defining the pathophysiology of the disease and developing approaches for improving the quality of life of the patients and their families.

## PEDIATRIC AIDS

Question. Recently there have been several reports indicating that an increasing number of young women are becoming infected with the AIDS virus and passing it on to their unborn infants, causing potential heart and lung problems. Does the NHLBI plan to address the problem of these complications in infants?

Answer. Among the most common life threatening complications in infants who suffer from AIDS, as in adults, are pulmonary infections. In addition, infants and children with AIDS, frequently develop an infiltrative lung condition, lymphoid interstitial pneumonia/pulmonary lymphocytic hyperplasia (LIP/PLH complex), rarely seen in adults. It is possible that LIP/PLH complex results from infection with the human immunodeficiency virus (HIV) alone or in combination with other infectious agents. Since the precise cause of LIP/PLH complex is unknown, treatment is directed at relieving symptoms. Even less is known about cardiac abnormalities associated with HIV infection, but abnormal echocardiograms and heart failure have been observed in many pediatric AIDS patients. The cause of these heart abnormalities and the extent to which they occur needs to be determined.

The Institute is currently planning a natural history study of the pulmonary and cardiac complications of HIV infection in infants and young children. Information obtained from this study should help provide a foundation for preventing and treating the lung and heart diseases that occur in association with HIV infection.

## AIDS

Question. Pulmonary disease is the major complication resulting from infection with the AIDS virus. Does the National Heart, Lung, and Blood Institute have a program to track the various pulmonary complications that result from AIDS virus infection?

Answer. Pulmonary infections as a group are the most commonly recognized life threatening disorders in persons infected with the AIDS virus. While a great deal of information about the types and occurrence of these pulmonary complications has been obtained since the AIDS epidemic began, in many instances the true spectrum of complications is not well known, and may be changing. It may also be that with the various new treatments for Pneumocystis carinii pneumonia (PCP), the most common pulmonary complication in AIDS patients, changes its mode of presentation of these patients upon second and third episodes of PCP. It is evident that these aspects of the AIDS epidemic need to be followed.

As a result, in September 1987 the NHLBI in collaboration with the National Institute of Allergy and Infectious Diseases began a multicenter study to follow the types incidence, course and outcome of pulmonary complications in persons infected with the AIDS virus. It is anticipated that some 1,400 to 1,600 persons infected or at risk of being infected with the AIDS virus will be studied over a four year period. Specific pulmonary complications and treatment regimens of the study participants will be monitored and will permit gathering of information on the shifting patterns of the various complications associated with AIDS virus infection. In addition, pulmonary function measurements on each study participant will be made routinely. Collection of these measurements is expected to yield information on whether early detection of changes in pulmonary function and consequently earlier treatment of their lung diseases is associated with a less severe course and reduced mortality.

## ASPIRIN AND HEART DISEASE

Question. Recent reports have been mixed as to the efficacy of using aspirin to prevent heart disease. What is the NHLBI position on the routine use of aspirin by the American public to prevent heart disease?

Answer. Clinical trials have established the efficacy of chronic aspirin treatment for prevention of cardiovascular events in patients who have documented coronary artery disease and no contraindication to aspirin treatment. However, in the population at large, in those without a confirmed diagnosis of cardiovascular disease, the role of aspirin therapy for prevention purposes is less clear.

People at high risk of developing heart disease, or those already with heart disease, might benefit from aspirin. Others, including those with uncontrolled hypertension, might find that the side effects outweigh the benefits. These trade-offs must be considered. The Institute recommends that people see their physicians before deciding to take aspirin on a regular basis. Taking aspirin is not a substitute for risk factor modification. Cessation of cigarette smoking and blood pressure and cholesterol reduction, where appropriate, remain key.

Question. What are the pros and cons of this therapy?

Answer. Aspirin use in the general population may prevent many cardiovascular disease events and deaths associated with acute thrombosis including heart attack, stroke, and obstruction to circulation in the extremities. However, adverse reactions to aspirin may be life threatening. These adverse effects include allergic reactions and serious hemorrhage in the gastrointestinal tract or brain. The pros and cons will be different according to age, sex, the dose of aspirin used, and the person's overall medical condition. Additional information is needed to evaluate the trade-offs between cardiovascular events prevented and adverse events induced by aspirin.

## ANTI-CLOTTING DRUGS

Question. In November 1987, the Food and Drug Administration approved the drug tPA (tissue plasminogen activator) as an anti-clotting drug for administration following heart attacks. The Health Care Financing Administration (HCFA) announced in March 1988 that it will not pay for the use of tPA for Medicare patients. The HCFA decision was based on the drug's cost (ten times that of similar drugs) and the lack of evidence that tPA is any more effective than comparable drugs. What is the position of your Institute on the efficacy of this drug over others in dissolving blood clots and preventing a permanent damage to the heart muscle?

Answer. Thrombolytic therapy for heart attacks has become a very active field of research. The NHLBI initiated a study in 1983 to evaluate the available thrombolytic agents. The leading candidate drugs were streptokinase (SK), made from streptococcal bacteria, and recombinant tissue-type plasminogen activator (rt-PA), made from a natural human clot dissolving agent. In a double-blind study, rt-PA was found to dissolve twice as many coronary artery clots at a substantially faster rate than streptokinase. Bleeding complications occurred with similar frequency. Given this evidence of better thrombolytic performance, rt-PA was selected for further evaluation.

The NHLBI study was not designed to evaluate the effect of these agents on heart function or survival. Other studies have demonstrated improved heart function or survival with rt-PA compared with placebo. Although early studies produced conflicting results, more recent research has also demonstrated improved heart function or survival with streptokinase compared with placebo. Direct comparison between rt-PA and streptokinase for improved heart function and survival are underway in Europe. Until more information becomes available, the relative safety and efficacy of these two agents will continue to be unsettled.

## HEART TRANSPLANT

Question. New evidence suggests that children who received heart transplants are prone to atherosclerosis and have a worse survival rate than transplanted adults. Why is this true?

Answer. Although the numbers are small and subject to statistical error, children do not have a worse survival rate than transplanted adults. In fact, data from the Registry of the International Society for Heart Transplantation show that the survival rate for patients 0-18 years of age is no different from that for adults. There is a type of atherosclerosis, called accelerated atherosclerosis, which is seen in transplant patients of all ages. There is no evidence to indicate that it occurs more frequently in children who have received transplants than in adults.

Question. What is being done by NHLBI and NICHHD to study this problem?

Answer. Accelerated atherosclerosis is the most serious threat to long-term survival following heart transplantation for patients of all ages. It affects 36-44% of all heart transplant patients. Its etiology is unknown and there is no therapy proven to be effective either for prevention or treatment. Although several investigators are studying this problem, the NHLBI is convinced that a concerted effort needs to be made to encourage investigators to address the problem. Therefore, the NHLBI is developing a program designed to study various aspects of accelerated atherosclerosis in animal models and/or humans.

## NATIONAL CHOLESTEROL EDUCATION PROGRAM

Question. NHLBI initiated the National Cholesterol Education Program in 1985 to coordinate national efforts to reduce high blood cholesterol, one of the major modifiable risk factors for coronary heart disease. What is the current status of this program?

Answer. The program is very active. Recently it issued a report providing health professionals with a detailed algorithm for detecting and treating individuals with elevated blood cholesterol levels. It has a public education effort urging the public to know and understand the significance of their cholesterol levels. Many indicators, such as patient visits, the number of prescriptions written, and the number of inquiries from the public, suggest that these and other professional and public education activities are being heard and acted upon.

Question. What is this program costing annually?

Answer. Not counting the research which provides the scientific foundation for the program, there are approximately $1.5 million directly identified with this program. Because other supporting activities and dollars are for generic activities such as information services and staff support, it is sometimes difficult to determine exactly how much is associated with cholesterol education and, for example, with high blood pressure education. The activities of the program stimulate many other agencies and organizations to invest their staff time and budget dollars to support the goals of the national effort. The total accumulation of this outside investment provides most of the support for the program.

Question. Tell us about the National Cholesterol Conference scheduled for November 1988.

Answer. The conference will be a forum for providing current science related to cholesterol, and giving attention to how science can be translated into practical and effective program activity, whether in the health care setting or in the conference. There is considerable interest in the conference. It will be attended by scientists, clinicians, public health officials, health educators and communicators. We anticipate that the attendance will be about 1,000 people from all around the country. The conference is based on the National High Blood Pressure Conference model and we expect it to be a forum for stimulating new ideas and efforts. It will be held in Crystal City, VA from November 9-11.

## FISH OILS

Question. What is the status of the research and thus scientific opinion on the theory of whether fish oil (i.e., omega-3 fatty acids) prevents plaque buildup in arteries and helps prevention of heart attacks and strokes?

Answer. While consumption of omega-3 fatty acids (fish oil) has been shown to result in a number of metabolic and physiological alterations, including incorporation of omega-3 fatty acids into circulating lipid complexes and into membrane lipids, decreases in both total plasma cholesterol or LDL-cholesterol have been found to be either modest or nonexistent. However, the lack of systematic studies of omega-3 fatty acids and their relationship with plaque buildup in arteries prevents definitive conclusions concerning their effects on human health. To date, investigators have noted few side effects resulting from human consumption of omega-3 fatty acids, but animal studies suggest the potential for several deleterious effects. Long-term evaluation of products containing these fatty acids, especially fish oil concentrates and derivatives, is needed.

Although investigators reported mixed results on plasma cholesterol levels, the lack of systematic studies of omega-3 fatty acids on plaque buildup in arteries prevents definitive conclusions about their effects on human health. Although investigators noted few side effects resulting from human consumption of omega-3 fatty acids, animal studies indicate the potential for several deleterious effects. Long-term evaluation of products containing these fatty acids, especially fish oil concentrates and derivatives, is needed.

Question. How does use of the fish oil tablets compare with fish consumption in terms of the health/heart benefits?

Answer. The use of fish oil supplements for high-risk blood cholesterol levels is not recommended because it is not known whether long-term ingestion may lead to undesirable side effects.

Consumption of omega-3 fatty acids is to be differentiated from that of fish. Some fish are rich in omega-3 fatty acids while others are not. Epidemiologic data suggests that frequent consumption of fish of any type, seemingly independent of omega-3 fatty acids, is associated with reduced CHD risk. Whether or not this is true, fish is a good food choice in dietary patterns since it is low in saturated fat.

## AUTOTRANSFUSION

Question. Autotransfusion is the reinfusion of a patient's own blood, a procedure that has become popular in recent years due to the fear of AIDS and other limitations of banked blood (such as time savings, cost reduction, transfusion reactions, and religious prohibition. Is this procedure just a fad or does it offer an appropriate alternative for elective patients in the future?

Answer. Reinfusion of one's own blood is the safest form of transfusion. Donating one's own blood in advance of planned surgery has been an excellent idea for many years, provided the patient is well enough to tolerate that donation. This option has become used more often since the concern with transfusion-associated infectious disease has increased. With advanced planning, it is possible to donate up to four or more units prior to surgery. Thus many operations can be done without using blood from the blood bank. Because predeposit donation is not an option for emergency surgery and because many patients are too ill to tolerate blood donation, there is a limit on the proportion of patients for which this form of autotransfusion is an option, perhaps ten to twenty percent at most. Thus, there continues to be a need for safe blood donors.

In June, the NHLBI is cosponsoring with the NIH Office of Medical Applications of Research, the Food and Drug Administration (FDA) and the NIH Clinical Center Blood Bank a Consensus Development Conference on Perioperative Red Cell Transfusions. A discussion of the place of autotransfusion will be part of that conference.

## ARTIFICIAL BLOOD

Question. What is the current status on research and use of artificial blood?

Answer. Research on artificial blood is currently proceeding along two different lines. One area is concerned with the development of oxygen-carrying red cell substitutes consisting of perfluorochemical (PFC) emulsions. A PFC emulsion, trade name Fluosol-DA, has been evaluated in human clinical studies and shown to be ineffective in the treatment of acute anemia. Newer PFC preparations are being developed and evaluated. One such preparation, developed in an Institute-sponsored program, does not need to be stored frozen, as other emulsions. Furthermore, it is not toxic and can carry larger quantities of oxygen than previous preparations.

The second area of research is focused on the development of substitutes that are hemoglobin-based. Because simple hemoglobin solutions are eliminated too rapidly by the kidneys to be effective, the hemoglobin molecules are joined together as polymers to reduce their rate of elimination and increase the time that they remain in the circulation. These polymers are modified to enhance their ability to carry oxygen, a quality that is impaired when hemoglobin is not in red blood cells. A polymerized hemoglobin preparation, shown to be effective in baboons, is undergoing clinical trials in humans. Another promising approach involves encapsulation of hemoglobin molecules, which prevents rapid elimination from the circulation and allows satisfactory oxygen transport. These second-generation formulations offer opportunities for future clinical applications.

In June, the NHLBI is cosponsoring with the NIH Office of Medical Applications of Research, the FDA and the NIH Clinical Center Blood Bank a Consensus Development Conference on Perioperative Red Cell Transfusions. A discussion of the place of blood substitutes will be part of that conference.

## AIDS

Question. The most commonly recognized complications that result from HIV infections are pulmonary disorders, and pulmonary disorders are present almost universally in children with AIDS. What progress is being made in treating pediatric AIDS cases?

Answer. The Institute is currently coordinating an effort with other NIH Institutes to implement a natural history study of the pulmonary and cardiac complications of HIV infection in infants and young children. Information obtained from this study should help provide a foundation for preventing and treating the lung and heart complications associated with pediatric AIDS.

### BLOOD SUPPLY

Question. In the decade between 1971 and 1980 there was a 40 percent increase in the amount of blood collected, but a 100 percent increase in the number of blood units transfused. Since then, the demand for blood has increased, largely as a result of AIDS, and the supply of blood has decreased also as a result of AIDS because of the fear of some that they can get AIDS by giving blood. I understand you are developing a new program--the National Blood Resources' Education Program-- to ensure an adequate and safe supply of blood. What is the current status of the blood supply and the new education program?

Answer. There are currently heavy demands on the blood supply because of increasing need for blood and blood products. There is a slight risk of transmitting the AIDS virus through blood even though it is screened. The chance of HIV transmission ranges from 1 in 40,000 units to 1 in 100,000 units of blood. For these reasons the Institute felt that a blood resource education program was absolutely essential. Therefore, the National Blood Resource Education Program (NBREP) was launched by the NHLBI in 1987. The program has two goals: to ensure an adequate supply of safe blood and blood components to meet the Nation's needs; and to ensure that blood and blood components are transfused only when therapeutically appropriate.

### ARTIFICIAL HEART

Question. The Institute is funding research and development for an artificial heart that would free patients from the bulky support equipment of current heart devices. When do you expect such a device would be ready for the first transplant operation?

Answer. The development of a fully implantable total artificial heart device will not be ready for human transplantation for 10 to 15 years. For this reason, the Institute will also initiate testing of a left ventricular assist device in humans. A prototype device, which is now undergoing final evaluation in bench tests, will probably be ready for experimental human implantation in 2 or 3 years.

### ASTHMA

Question. Recent reports show an increase in deaths due to asthma. To what do you attribute this increase?

Answer. Asthma mortality has increased slightly in many western countries, including the U. S. Whether this increase represents a real trend or is simply a matter of background fluctuations in rates is not clear. Nevertheless, it is cause for concern at a time when mortality rates from other chronic diseases are declining. Data indicate a significant increase in asthma morbidity. Between 1965 and 1983, hospital discharges for asthma more than doubled in all age groups, but for children, the number of hospitalizations increased more than five fold. The increase is of importance because hospital rates for all other diseases are decreasing, and a variety of effective drugs are available to manage asthma.

The reasons for the increases in asthma morbidity and mortality are not understood. Available data are now being examined carefully. It is clear that research on the causes of fatal asthma, on the reasons for hospitalizations, and on the optimal methods of therapy for the condition is required.

Question. What can be done to stem this increase?

Answer. Although the specific reasons for the increasing rates of asthma mortality and morbidity are not known, many of the benefits of improved therapeutic agents for asthma are not being experienced by patients. Most asthma can be controlled if the patient receives appropriate therapy and manages the condition carefully. However, asthma is often a complicated disease to manage, and patients must learn self-management strategies if unnecessary trips to the medical system are to be avoided.

The NHLBI has developed several educational programs for children with asthma and their families that have been successful in reducing number of attacks, visits to emergency rooms, and days lost from school. These programs are especially useful for those who are frequent users of emergency health care services. Programs are being developed and evaluated to offer self-management education to various populations in various settings. These programs need wide implementation and physicians need to assure that their patients are educated to manage their disease. The NHLBI will be conducting a workshop in 1988 to devise a national strategy for assuring the widespread dissemination of asthma education to both physicians and patients.

## ALZHEIMER'S DIASEASE/DIAGNOSTIC RADIOLOGY

Question. From all the information we have, it seems that the difficulty in making an accurate diagnosis of Alzheimer's disease is a major obstacle in finding an effective treatment. But it sounds as though some of the new technologies--like PET scans and magnetic imaging--might help lead to a reliable diagnostic test. Would you give us a quick update on diagnostic imaging?

Answer. As the technologies and instrumentation for brain imaging improves, physicians will have the necessary tools to improve the accuracy of diagnosing Alzheimer's disease. The new and constantly improving brain imaging technologies, such as CT scans, PET, SPECT and MRI provide different information about structural and functional changes in the brain. PET scans have begun to yield extremely valuable information about brain glucose utilization. Recent findings have allowed scientists to correlate memory disorders in AD with reductions in glucose utilization in specific parts of the brain. MRI scans allow physicians to visualize the live brain in great detail just as a fine black and white picture of the inside of the brain, as though the hair and the bones of the head were not there. *In vitro* spectral MRI has been shown to detect abnormal brain cell membrane constituents. Within a short time, these techniques will allow physicians to detect reversible or treatable forms of dementia early in the course of the disease.

Question. It sounds as though these new techniques hold a lot of promise.

Answer. Brain imaging technologies in association with other clinical tests hold great promise in improving the differential diagnosis of AD. At present, brain imaging alone cannot render an accurate diagnosis. But, as in vivo spectral MRI techniques become standardized and validated, very early and accurate diagnostic information should be possible. In addition, a recent study in our intramural dementia research program has shown that sequential CT scans of the brain can yield a clear distinction between Alzheimer changes and normal aging changes.

Question. How much of your budget is allocated to research on diagnostic imaging?

Answer. The NIA has identified research related to improving brain imaging as a high priority area for emphasis in FY 1988. At present NIA devotes $3,400,000 to this area of research. We expect to increase this investment in FY 1989 to $4,400,000.

Question. Does your Advisory Board include a radiologist?

Answer. Our National Advisory Council on Aging does not include a radiologist. However, in 1983 the NIA sponsored a major workshop on the Diagnosis of AD. This meeting was intended to be a research planning workshop which identified important scientific opportunities in the area of diagnosis. The workshop had several panels of experts including Neuroradiology, Neuropathology, Neurology, Psychiatry, Neurochemistry and Neuropsychology. At all the NIA sponsored workshops on AD neuroradiology is invariably represented.

Question. My concern is that we have enough qualified people exploring every avenue of research. Are we training people in the field of radiology?

Answer. The NIA has several training and research career development mechanisms available for research workers from all medical and behavioral specialty areas, including neuroradiology. The mechanisms include the National Research Service Awards, Clinical Investigator Awards, Academic Awards, and the Physician Scientist Awards.

Question. Does your Institute have some training slots set aside for radiologists?

Answer. NIA does not have any specific training slots set aside for any medical specialty area. However, many radiologists do obtain research training by working on problems related to AD through the NIA funded Alzheimer's Disease Research Centers.

The issue of well qualified researchers interested in AD is an acute problem. The NIA has made a special effort to increase the number of well qualified researchers. A special initiative will be launched by NIA to stimulate further training in key areas such as neuropathology, behavioral neurology, neuroradiology, nursing researchers and other care providers.

ALZHEIMER'S FUNDING

Question. In your testimony last year you stated that research projects supported by your Institute have made significant progress in addressing Alzheimer's disease in terms of the diagnosis, treatment, and prevention. Can you give us the total NIH budget for Alzheimer's disease?

Answer. The total NIH budget for Alzheimer's disease is estimated to be $85,362,000 for FY 1989, of which $58,667,000 is provided by NIA.

Question. What percent of the total NIH budget is reserved for Alzheimer's disease research?

Answer. Approximately 1.3% of the total NIH budget is directed toward Alzheimer's disease research in FY 1989.

Question. How does this percent differ from last year?

Answer. The same percentage of the total NIH budget is reserved for FY 1988.

Question. It is our understanding that between 2.5 and 3 million people in the United States are affected with Alzheimer's disease, and that the total cost of care for these individuals is roughly $90 billion. What has your Institute done during the past year to reduce this number?

Answer. While progress is being made on many fronts in understanding Alzheimer's disease, we do not yet know the cause or causes. Methods for preventing the occurrence of the disease or permanently interrupting its course are not available yet.

Treatment of Alzheimer's disease (AD) is an important priority for NIA. Many scientists are directing their efforts to develop pharmacologic, behavioral and environmental interventions to ameliorate the symptoms of the disease and to reduce the burden to the families of the victims.

The NIA, in a unique and fruitful collaboration with the Warner-Lambert Company and the Alzheimer's Disease and Related Disorders Association, initiated the multi-center clinical trial of tetrahydroaminoacridine (THA). Should the efficacy and safety of THA be confirmed, it would be a palliative treatment only, since the underlying process of degeneration of cholinergic neurons is not altered by the anticholinesterase activity of THA. However, even modest improvement in functioning by Alzheimer victims would be very rewarding.

Alzheimer's disease is not restricted to deficits of the cholinergic system but also of other neuronal transmitters. Thus new therapeutic strategies are being designed which accommodate the diverse neurochemical deficits seen in the AD population by restoring the functional integrity of a number of affected systems. Since the principal pathological changes in AD may involve neuronal membrane constituents and the functioning of cytoskeletal organelles, new treatment strategies will focus on developing pharmacological agents which maintain the integrity of these elements of a nerve cell. The possibility of even a short extension of normal and productive life of both the AD patient and his/her family is very important. The search for other treatments for AD needs to continue as a high national priority.

Question. Where do you see this figure ($90 billion) going, i.e., an increase before a decrease, remain the same? Why?

Answer. The public health burden of Alzheimer's disease is determined by the rate at which new cases occur in the population and the length of time between the beginning of symptoms and death. Alzheimer's disease is clearly an age-associated illness in that the risk of developing the disease increases with advancing age. This is particularly disturbing when coupled with the profound demographic shift which is underway in the U.S. and in much of the rest of the world. The population of our country is rapidly growing older. Unless the means are discovered to prevent the onset and to cure those who are already ill, the cost of Alzheimer's disease to our society will continue to increase at a stunning rate.

## CENTERS

Question. It seems like the most appropriate method to gain more insight on the cause, diagnosis, and treatment of Alzheimer's disease is to continue to establish centers. Is this an accurate statement?

Answer. The Alzheimer's Disease Research Centers (ADRC's) program supports basic and clinical research, research training and public information and outreach programs. Some of the more notable achievements of the ADRC's include:

- Rapid exchange of scientific information as well as for initiating collaboration among scientists from different centers.
- Formation of a clinical data committee which has begun to standardize clinical data gathering in the ten centers and to develop common protocols for diagnosis.
- The pilot project program through the centers has become instrumental in breaking new and innovative ground in exploring the cause of Alzheimer's disease (AD), such as the seminal studies in identifying the genetic factors in AD.
- Identifying the potential location of the Alzheimer's disease gene has progressed at a considerably faster rate than would have been possible without the ADRC's.
- Standardization of criteria for the neuropathological evaluation of the AD patients' brain.
- The ADRC's were instrumental in launching the THA clinical trial on very short notice.

One of the major strengths of the Alzheimer's Disease Research Centers program has been its ability to bring together scientists from many different disciplines to attack a common problem. The eventual unraveling of the disease and the development of treatments will continue to require such a concentration of multi-disciplinary efforts linked by appropriate clinical, laboratory and neuropathologic resources. The ADRC's have become an exceptional vehicle for the rapid exchange and transfer of scientific information and for facilitating collaboration between investigators.

Question. Could you tell us how many Alzheimer's research centers you are currently supporting?

Answer. The NIA is currently funding ten Alzheimer's Disease Research Centers. In FY 1988 we expect to add two additional centers.

Question. What is the average annual budget for each center?

Answer. The average annual budget for each center is about $1.2 million.

Question. Are there plans to establish more centers?

Answer. The NIA is presently supporting ten Alzheimer's Disease Research Centers (ADRC's) and will fund two additional ADRC's by the end of FY 1988. It is our professional judgement that an additional four centers would be useful to expand the clinical and research base on AD; open opportunities for new collaborative research initiatives within the ADRC program; increase the national effort to provide more sophisticated diagnostic procedures to wider segments of the U.S. population; provide resources for more specialized training of health care providers; and enhance public information efforts. Funding additional centers, however, would require offsets against other public health activities consistent with the Bipartisan Budget Agreement.

Question. Could you explain how these centers operate, i.e., does each center have a specific area of research and works independently, or are the research efforts done in collaboration with other centers to avoid duplication?

Answer. An ADRC is an identifiable organizational unit formed by a single university medical center or a consortium of cooperating institutions, including the university affiliated centers. There must be strong cooperation and communication among all involved personnel of all professional disciplines.

The ADRC's perform the following specific functions:

- Research: conduct basic and clinical research in the fields of Alzheimer's disease and its management;

- Research Training: train postdoctoral fellows, physicians, and health professionals for research in Alzheimer's disease and related dementing disorders of older people; and

- Information Transfer: transfer advances in the field of Alzheimer's disease research with the least delay into improved care for the Alzheimer's patient through outreach programs to the regional community, continuing education, and information programs.

The ADRC grant provides support for:

- new research projects;
- pilot or feasibility studies;
- administrative clinical, neuropathological and research training and information transfer core resources; and
- integration of activities with other centers.

Each ADRC has its own unique research agenda based upon the expertise of the investigators. Twice annually the Directors of the ADRC's and selected members of the research teams meet to discuss research progress and to coordinate their research efforts. As an important example of collaboration, the ADRC Directors have recently formed a Clinical Trials Committee which will consider the development of trials of promising therapeutic agents and interventions and coordinate the efforts of all sites.

Question. Can you tell us the status of the ten centers of excellence for research and training you had planned to establish?

Answer. NIA is prepared to initiate a program of Geriatric Research and Training Centers in FY 1989. Establishment of such centers was recommended by the Institute of Medicine to develop the academic leadership needed to train enough professionals to serve the growing health care needs of older persons. At least ten institutions in the U.S. have the skills and facilities to develop such centers. Establishing these will require authorization for additional NIA centers, as well as adequate funds. The estimated cost per center is approximately $1 million per year. Initiating up to five centers in FY 1989 would permit their establishment at the very best institutions. The experience from such centers would be very valuable in guiding other institutions in planning their centers programs.

## RESEARCH EFFORTS

Question. You have indicated that research efforts over the past few years have provided information that enhances the prospects for the ultimate understanding of Alzheimer's disease and potential treatment for some of the serious symptoms. Can you apprise us on the status of these various research efforts?

Answer. In research on biomarkers of aging, important findings by several NIA grantees indicate the potential for biomedical diagnostic tests for AD based upon the detection of specific biological markers. Most of these can be performed only on postmortem tissues. There is a need to search for antemortem diagnostic biochemical markers for AD, especially for the early stages of the pathogenesis when potential inventions would be the most effective. Potential markers could include abnormal brain proteins, abnormal production of amyloid and amyloid precursor molecules, cellular changes detectable in non-neuronal tissue such as fibroblasts or lymphocytes, identification and location of genetic markers and gene products. Recently two breakthroughs have provided scientists the encouragement that finding such specific biochemical markers of AD is a realistic expectation. One investigator at Albert Einstein College of Medicine has identified a specific protein, A-68, which is found in AD patients. This lead should enable scientists to develop an easy-to-administer diagnostic test. The second finding from Cornell Medical College, which is in its very early stages, shows that cell cultures derived from the skin of AD patients reacts to antibodies in a unique manner. This approach, if confirmed, will not only provide scientists an easy and reliable way to diagnose AD but also will provide an important tool for studying how abnormal proteins are found in AD.

In research on the tetrahydroaminoacridine (THA) drug, the NIA, with the Warner-Lambert Company and the Alzheimer's Disease and Related Disorders Association, initiated a multi-center clinical trial of THA by virtue of the readiness of the 10 ADRC's to begin such a study promptly. As of October 23, 1987, 50 patients had been entered into the clinical trial and were taking THA. On that date, the trial was temporarily suspended due to findings of elevations of liver enzymes in 14 patients exposed to THA during the dose-finding phase. The elevations (>100 IU/L) were limited to the two highest doses of THA base (120 mg and 160 mg). No associated clinical disorders were observed. The trial was resumed in February using a modified protocol with the lower doses of THA which had shown no toxicity. We expect to have definitive information on the efficacy of THA by spring 1989.

Question. What is the status of the cross-cultural and cross-national projects?

Answer. In June 1987, NIH and the World Health Organization (WHO) signed a formal agreement creating the Special Program for Research on Aging (SPRA). The SPRA occupies space within NIA and works in close cooperation with counterpart staff of NIA.

The WHO Advisory Committee on Health has identified, in addition to Alzheimer's disease and other age-associated dementias, three other high scientific priorities: the epidemiology of healthy aging; aging and immune function; and nutritional aspects of osteoporosis. Scientific Steering Committees have been formed for each of the four areas, and planning meetings have been held. Further planning meetings are scheduled throughout the coming months aimed toward presentation of research plans at a meeting of the SPRA Scientific Advisory Committee, scheduled for the fall.

As mandated by Congress, NIA and the Agency for International Development (AID) have been working to identify areas of mutual interest for cooperative research activities in aging. Thus far, AID has provided limited and partial support for the SPRA scientific planning meetings, including a planning session on cross-cultural studies of AD and development of a data base on demography of less developed countries emphasizing the population aged 65 and older. Discussion is continuing concerning support by AID, through NIA, of specific promising cross-cultural comparative studies of aging in developing and developed countries.

Workshops on population trends in aging were supported by the National Institutes of Health, National Center for Health Statistics (NCHS), and NIA. Other international activities include formal agreements which have brought scientists from other nations together through visiting scientist programs, and binational symposia with Italy and Israel held in September and November 1987, respectively. The NIA also supports collaborative programs between United States investigators and investigators in many countries, including the People's Republic of China, Japan, Canada, the United Kingdom, Israel, Finland, and Australia. Such international collaborations are expected to provide answers to the possible cause(s) of Alzheimer's disease and osteoporosis since the incidence appears to differ in these countries as compared to the United States and compared to each other.

Other larger-range opportunities exist for collaborative and cooperative international and cross-cultural research on aging. For example, the NIA is currently working on development of a field station for studies of older persons who emigrated from the Pacific Basin Area to Hawaii and the West Coast, in comparison to their relatives still in their home countries, and a possible similar approach for comparative studies in Latin America and Southern United States, as well as a study of closely related persons in Calabria, Italy, and East Boston, Massachusetts. Cross-national comparisons of the incidence rates in distinct subpopulations, such as rural versus urban, or in cohorts of individuals who have been exposed to certain environmental toxins or suffered head injury, may identify potential risk factors for the dementias.

Question. What is the status of the behavioral and life-style factors studies?

Answer. NIA funded research is examining social and behavioral factors in the care of AD patients and in the reduction of caregiver burdens. A few generalizations can be made regarding the patterns of processes of family caregiving, but additional research is needed to fill in the picture and to provide a basis for intervention strategies and policies when needed. We know, for example, that family caregivers are primarily women, mainly wives and daughters. However, there is increasing recognition of the important role and special situation of spousal caregivers, typically one-half of whom are men. Spouse caregivers are usually the sole caregiver and are less likely to utilize formal services. We know that caregivers perform a wide variety of caregiving activities which are often found to be gender related with women performing more personal care and men performing financial management and home maintenance. It is clear that informal care outweighs formal services. The National Long-Term Care Survey indicates that less than 10 percent of caregivers use formal services. Research is questioning the assumption of a caregiving network: by and large, caregiving is not a shared task; most care is provided by one primary caregiver. There is clear evidence of depression among caregivers, especially among caregivers of Alzheimer's disease patients.

NIA has always been concerned with research on caregivers of AD patients as part of its more general emphasis on families of older persons and long-term care needs of older persons with chronic illnesses and disabilities. In response to the pressing need for more research on AD patients and their caregivers, NIA has intensified its research efforts on social and behavioral aspects of AD and related disorders such as:

- Social and behavioral strategies for managing AD patients in community and institutional settings.
- Assessment of different combinations of formal care and social services for AD victims and their caregivers.
- The nature and extent of caregiving burdens and factors predicting who will become caregivers with what consequences.
- Research on behavioral, social, and technological interventions and coping strategies that can reduce caregiver burden and stress.
- Forecasting future numbers of persons with AD and their long-term care needs and costs.

Question. Have you initiated any new clinical trials?

Answer. The NIA has not initiated any new major clinical trials for the treatment or management of Alzheimer's disease since the funding of the THA trial. However, there are several areas in which the NIA anticipates receiving proposals for clinical trials in FY 1989 or FY 1990:

A. Drug trials which address disease progression by attempting to correct more than one of the neurotransmitter deficits simultaneously.

B. Research on nerve growth factor (NGF) suggests that it may be required for the maintenance of functioning, as well as survival, of some particular neurons in the brain. Administration of NGF to AD patients may promote survival of these neurons and retard the memory loss seen in AD. Several research centers around the country are considering clinical trials of NGF for AD.

C. Clinical trials addressing the problems of secondary effects of drugs, since a major clinical problem in treatment and management is the lack of data-based guidelines for the use of drugs to control secondary symptoms such as agitation, aggression, depression, and sleeplessness. Each clinician is fundamentally conducting uncontrolled trials when treating his/her patients. An additional resulting problem is the production of delirium in older people as a result of the use of medications with anticholinergic and other transmitter effects. Delirium is associated with substantial mortality.

Many drugs have delirium producing properties, including the antipsychotics, tricyclic antidepressants and antiparkinsonian agents. But it is speculated that many other commonly used drugs have unrecognized anticholinergic activity. When multiple drugs are given, the risk for delirium as a simple result of the medications is compounded by individual differences in the ability to absorb, metabolize and excrete the drugs. Daily clinicians face the danger of causing a delirium in compromised older people when attempting to manage symptoms.

D. While a lack of information exists on how to pharmacologically manage secondary symptoms, the relative efficacy of behavioral interventions as contrasted and combined with pharmacological methods is an additional gap. Experience in other countries and cultures suggest that behavioral methods can be used to control the most troublesome symptoms of Alzheimer's disease and may alleviate the need for medications. Many important questions exist in the behavioral and environmental areas:

- What are the most useful behavioral techniques for controlling agitation and pacing, preservation, feeding problems, and toileting functions? Can the behavior change be maintained? How must the techniques change as the disease progresses?

- What are the most effective technological, behavioral or environmental interventions for preventing people from getting lost or wandering?

- What behavioral or environmental interventions can prevent "sundowning" or evening confusion?

E. Specialized Alzheimer's disease (AD) nursing home units are being developed in the absence of clear research-based information on efficacy. What are the characteristics of specialized Alzheimer's disease nursing home units which reduce the need for sedative or psychotropic drug use and restraints to control secondary symptoms? What is the impact of specialized AD units on the course of the cognitive and non-cognitive symptoms and on the duration of the illness? The impact of the onset of other common problems of nursing home patients, falls and fractures and incontinence, must be evaluated.

The characteristics of the specialized AD units to be considered include: physical structure, staffing, training of staff, regularity and extent of medical care and supervision, patient mix and activities programs. The selection of patients, certainty of diagnosis, stage of disease, cognitive and non-cognitive symptoms, and other medical illness must also be considered.

All treatment and management strategies must be subjected to vigorous investigations using the methods of clinical trials to determine that the patients benefit and that no harm results to the patient or the family.

## SHORTAGE OF PROFESSIONALS

Question. It is fairly well established that there is a serious shortage of professionals to work with the elderly population. What steps are you currently pursuing to eliminate this problem?

Answer. NIA's emphasis is on developing leaders who can in turn foster the development of enough professionals in various fields to serve the needs of older persons. NIA currently supports a variety of training and career development programs for this purpose. Most of these support awards to individuals, either for research training or for career development, including a mix of teaching, clinical responsibilities, and research.

Though these have supported the development of outstanding individuals, the number of leaders in geriatrics and gerontology has not nearly approached the needed number estimated in a recent report by the Institute of Medicine. In addition, many geriatric training programs are not currently headed by persons with the full range of clinical, teaching, and research abilities needed to provide optimal training to health professionals. As noted in the Institute of Medicine report, geriatric "Centers of Excellence", with a diversity of skilled personnel, are needed to provide enough leaders with this range of abilities. To implement this concept, NIA has developed plans for geriatric research and training centers. As shown by the impact of NIH centers programs on the progress of other specialties, this approach can produce significant results.

## NEW CLINICAL TRIALS

Question. In your testimony before this committee last year, you indicated that you had planned to initiate two new clinical trials in FY87. Could you tell us about those trials, were they initiated?

Answer. Yes, the Advanced Glaucoma Intervention Study and the Optic Neuritis Treatment Trial were initiated in 1987.

In advanced glaucoma, medication alone no longer reduces intraocular pressure adequately, and the patient experiences visual field defects in the affected eye. Recently, initial argon laser treatment has become popular as an alternative to the traditional method of surgery, trabeculectomy. Some patients, over time, need to undergo a sequence of surgical intervention. The Advanced Glaucoma Intervention Study is designed to determine which treatment sequence gives the best long-range outcome.

Optic neuritis is the most common acquired optic nerve disorder (excluding glaucoma) in the under-50 age group, and significant visual disability can be caused by this condition. Recurrent attacks of optic neuritis affect about 25 percent of patients. The Optic Neuritis Treatment Trial is designed to assess the value of corticosteroids in the treatment of this condition.

Question. Which of your five major areas (retinal and choroidal diseases, corneal diseases, cataract, glaucoma, and strabismus, amblyopia, and visual processing) of research are involved in these trials?

Answer. The Advanced Glaucoma Intervention Study is funded through the Glaucoma section of the Anterior Segment Diseases Program and the Optic Neuritis Treatment Trial is funded through the Strabismus, Amblyopia, and Visual Processing Program.

## AIDS

Question. Your Institute is participating in research on, or involved in combating AIDS. Would you explain the connection between AIDS and vision?

Answer. Ophthalmic disorders are commonly associated with the acquired immunodeficiency syndrome (AIDS), and blindness is among its many tragic complications. These ophthalmic clinical manifestations occur in patients with AIDS with sufficient frequency that basic research, clinical trials, and other epidemiological studies are warranted.

The immunosuppression that results from infection with the AIDS virus leads to the development of opportunistic infections within the eye. The most common of these is cytomegalovirus retinitis which occurs in 15-20 percent of patients with AIDS during the course of their illness. This progressive retinitis destroys the retina and can lead to visual loss and blindness. Other infections such as toxoplasmosis, herpes simplex, and herpes zoster can also involve the eye and lead to visual loss. In addition to these opportunistic infections, the AIDS virus has been shown to infect many ocular tissues. Unlike the infection that is seen in the brain, however, this type of infection appears to be asymptomatic.

Damage to the capillaries of the retina produces a condition known as "cotton wool" spots. Cotton wool spots in the retina are the most common ophthalmic manifestation of AIDS, occurring in at least 65 percent of patients. The cause of the capillary damage, which is probably present in all AIDS patients, has not been determined. Although cotton wool spots and associated minor retinal hemorrhages do not alter visual acuity, the presence of these retinal lesions may be related to other systemic alterations associated with human immunodeficiency virus (HIV) infection and may have prognostic significance.

## NEI INVOLVEMENT IN AIDS RESEARCH

Question. Could you please elaborate on the extent of your involvement with AIDS and provide a short statement regarding future plans on this issue.

Answer. In 1985 NEI intramural scientists reported the isolation of HIV in both the tears and conjunctival epithelium of AIDS patients. During the next year intramural research focused on pilot treatment studies of CMV retinitis. Laser treatment of active CMV lesions was found to be ineffective. Pilot studies of the drug dihydroxy propoxymethyl guanine (DHPG) have shown some promise and indicate that more extensive trials are warranted. In collaboration with other Institutes at the NIH, the intramural program is continuing to attempt to study these problems.

Currently, a small prospective clinical study is being conducted by NEI-supported extramural investigators to study the pathogenesis and prognostic implications of the non-progressive form of AIDS-related retinopathy (cotton wool patches, small hemorrhages) and the etiology and response to treatment of CMV and other viral retinopathies. To determine the viral agent responsible for the infection biopsies from patients with atypical viral retinitis are taken and analyzed using newly developed rapid immunodiagnostic techniques. Treatment includes antiviral therapy with a variety of drugs specifically selected for the type of virus found. Additionally, beta interferon and other agents are used in an attempt to to strengthen the immune system.

Other scientists supported by the NEI are using a mouse model of CMV retinitis to test the hypothesis that CMV infection becomes latent or dormant in the ocular tissues. These researchers are investigating the effect of the animal's age and the route of infection on CMV development within the eye. Localization of the sites of viral replication and latency in ocular tissues is also studied, as well as the role of immunosuppression in the development of tissue abnormalities and reactivation of the virus.

Plans for the future include a large extramural multicenter trial for the treatment of cytomegalovirus retinitis. Applications for other clinical trials and projects addressing epidemiologic and therapeutic questions will also be supported. Other drugs with activity against cytomegalovirus retinitis and different approaches to treating the disease, such as the injection of a drug directly into the eye or the combination of several antiviral drugs, will also be studied. Epidemiologic studies will attempt to identify risk factors leading to the development of AIDS related visual loss.

Question. Is your involvement at the intramural or the extramural level?

Answer. Both extramural and intramural NEI investigators are involved. Coordination of extramural activities within the NEI is the responsibility of the NEI AIDS Coordinator. The Associate Director for Extramural and Collaborative Programs coordinates collaborative efforts involving other institutes in concert with the Deputy Director, who serves on the NIH AIDS Executive Committee. Both, basic and clinical studies are being conducted in the intramural program.

Question. Was the $4,947,000 funding level sufficient?

Answer. At the present time we believe the 1989 NEI AIDS funding request is adequate.

Question. How were these funds used?

Answer. This money will support evaluations of new treatments for CMV retinitis, epidemiological studies to identify risk factors, and basic immunology, virology, and cell biology studies of the ocular complications of AIDS.

## VISION RESEARCH

Question. Currently your Institute supports approximately 80 percent of all vision research sponsored by the Federal Government and private organization in the U.S. Do you see this level of funding increasing or decreasing in the future?

Answer. The direct and indirect cost of eye diseases and blindness is approximately $20 billion a year. Eleven million Americans have visual impairment that can be corrected, more than 3 million people in the U.S. are blind in one eye, 1.7 million people have severe and irreversible visual impairment, and 500,000 Americans are legally blind. For the near future, I see the investment in eye research growing to continue to find cost effective ways to treat and prevent eye disease.

Question. How does the issue of prevention fit into this scheme?

Answer. Since the creation of the National Eye Institute (NEI) in 1968, the National Advisory Eye Council and the NEI have made prevention of eye disorders and diseases one of the primary goals of research supported by the Institute. This research is aimed not only at preventing diseases of the eye, but until that goal is achieved, at preventing their serious consequences--visual impairment, disability, and blindness.

Although few eye disorders can be prevented at present, significant progress is being made in understanding the basic mechanisms involved in the development of many. Increased knowledge will eventually lead to locating and interrupting the pathogenic process at an early stage. Currently, much of the prevention-related research is aimed at preventing sight loss and blindness, with particular emphasis on the following: hereditary and developmental degenerations of the retina, age related macular degeneration, diabetic retinopathy, retinopathy of prematurity, recurrent ocular infection from herpes simplex virus, and cataract. Also, development of new drugs and treatments related to the prevention of glaucoma, and research on the effects of visual deprivation related to the prevention of amblyopia and strabismus are emphasized.

The recently established National Eye Health Education Program (NEHEP) enhances knowledge transfer, another important aspect of our prevention program. Through NEHEP efforts to advise health care providers and the public of research results will be expanded considerably. Physicians and people with treatable eye diseases will learn that new procedures are available to reduce the risk of visual impairment and blindness.

In FY 1987 approximately 22.5 percent of the appropriation supported prevention and prevention-related research. It is expected that this funding level will remain relatively stable for the foreseeable future.

Question. What progress has been made in identifying bacteria that sometimes cause infections after intraocular lenses transplants?

Answer. Chronic, persistent intraocular inflammation (iritis or vitritis) complicates 1.1 percent of intraocular lens implantations according to a 1983 FDA study. Since these infections are often chronic in nature, the suggestion has been made that a number of such cases may be due to unrecognized low grade anaerobic bacterial infections. Propionibacterium acne, a common anaerobe on the lid margin, is now being investigated by NEI supported scientists for its ability to produce endophthalmitis. This organism has been also implicated in other inflammations following ocular surgery or trauma.

Question. What kind of eye care education programs have you initiated during the last year?

Answer. In addition to activities related to public information, scientific reporting, press relations, and special events, such as the NIH Centennial, the NEI has engaged in modest public education activities over the past year. These have primarily consisted of the daily handling of a wide variety of inquiries from members of the general public, patients and their families, health professionals, professional groups and associations, Congressional representatives, and the media. Many of these inquiries involve complex and sensitive topics and require extensive research to produce an appropriate response. A new system has recently been implemented to document all inquiries handled by the NEI in order to more accurately reflect the concerns and interests of the various publics that the Institute serves.

## DEMOGRAPHICS

Question. It is our understanding that roughly 3.3 million people in the United States are afflicted to some degree with vision impairment attributed to cataracts, another 1.5 to 2 million Americans affected with glaucoma, and roughly 45,000 people completely lose their sight each year.

Could you tell us what kind of cost figures are involved in caring for these individuals?

Answer. Based on an analysis of the total economic costs of visual disorders and blindness for the year 1981, these costs are estimated to be $19.5 billion for the year 1988. Although these figures include costs for eye examinations, treatment, hospitalization, nursing home care, rehabilitative services, and lost earnings, they do not assess the impact of visual disorders and blindness on quality of life. The NEI is currently planning a workshop to evaluate various scales for measuring the effect of visual disability and blindness on the quality of life so that future cost analyses can be made in human as well as financial terms.

Question. What specifically are you doing in an attempt to decrease these numbers?

Answer. NEI supported scientists researching the cause, natural history, prevention, diagnosis and treatment of eye diseases and disorders NEI supported scientists find new and better ways to limit and sometimes reverse the statistics that you have cited. Specific initiatives for cataract and glaucoma include the following:

Cataract To understand the opacity of the lens seen in cataract, one must evaluate the conditions which maintain the transparency of the normal lens. Therefore, considerable attention is given to chemical and biophysical studies of the healthy lens. According to one theory, the oxidation hypothesis, light enters the eye and the lens and causes a series of chemical reactions that transform normal oxygen into more active molecules. These oxygen containing molecules damage the lens and cause cataract. If this hypothesis is correct, it might be possible to develop methods to block the formation or activity of the oxygen-containing molecules and thus prevent cataract formation.

Projects aimed at understanding the mechanisms that give rise to lens growth and cellular differentiation represent another approach to preventing cataract. Through these studies scientists are exploring physiological factors that may be associated with the degenerative processes, seen in the aging lens. Other discoveries, for instance, the identification of a sensitive marker for age related cataract, portend well for the eventual early detection and prevention of cataracts.

Finally, the NEI is supporting epidemiological studies of senile cataract, the most common type of cataract. Nutritional status, medical history of cardiovascular disease or diabetes, ocular pathology, family history of cataract, sunlight exposure, drug, alcohol or tobacco use, and demographic characteristics will be examined to identify factors which may predispose individuals to the development of this disease.

Glaucoma Since significant optic nerve injury precedes and accompanies initial recognition of visual field loss in glaucoma, research efforts are devoted to learning how to protect the optic nerve, improving methods for lowering intraocular pressure and developing methods for very early detection of glaucoma and for predicting its clinical course.

New emphasis is being given to solving intractable problems associated with primary open-angle glaucoma by encouraging application of the latest techniques from the fields of molecular biology, cell biology, immunology, and epidemiology. These sciences are being brought to bear particularly to explain the blockage of normal fluid outflow from the eye that occurs in glaucoma. Investigators are trying to determine precisely how and when the optic nerve is affected by glaucoma. They are also trying to learn whether or not lowering intraocular pressure through drugs and surgery that facilitate fluid outflow, actually prevents the optic nerve damage that causes visual loss in this disease. The question of individual susceptibilities to different levels of intraocular pressure is also being investigated.

Epidemiological studies offer another valuable approach to understanding eye disease. Open angle glaucoma is a major cause of visual impairment in blacks and blindness due to glaucoma is eight times higher in blacks than in whites. Since the reasons for this are not well understood, an epidemiological study has been initiated in Barbados, West Indies where most citizens are of African descent and a high rate of glaucoma has been reported. This study will provide an accurate measure of the prevalence of glaucoma in this population, and will define segments of the population at high risk for development of glaucoma who can be targeted for preventive intervention.

Question. Have you established any goals or timetables regarding the previous question: If not, why not?

Answer. Prevention of blinding and disabling eye conditions is the NEI's highest priority research goal. An outline for attaining this goal set forth in the Institute's comprehensive research plan which includes recommendations from experts in vision research regarding areas of study which provide an opportunity for reaching more specific goals and objectives in each program. These objectives are based on a project by project review and evaluation of the entire NEI program and accomplishments. Recommendations concerning program development for achieving objectives are consistent with current research needs, opportunities, and approaches.

## CANCER CENTERS

Question. Dr. DeVita, we understand that the President's budget for fiscal year 1989 for the National Cancer Institute would "straightline" the cancer centers program.

Could you tell us what the level for cancer center program funding is for fiscal year 1988? And, if the program is straightlined, what that means in terms of a percentage reduction from peer-reviewed levels for competing and non-competing core grants?

Answer. In FY 1988, the National Cancer Institute plans to obligate approximately $100.6 million for cancer center grants. If centers are straightlined into FY 1989, we project that non-competing centers will be paid at their commitment of record level, a level which reflects adjustments from previous year's council recommended levels. Competing centers will be reduced by approximately 31 percent from the recommended level. However, based on program considerations it may be more advisable to reduce the number of centers and fund the remaining centers at closer to recommended levels.

Question. I assume you can prevent such severe administrative reductions by taking other actions, such as causing some cancer centers up for renewal funding to be dropped from the program. Could you indicate to us the likely scenario in this case?

Answer. With the assistance of our advisory boards, we are exploring this option. It is interesting to note that there has been concern expressed by our advisory committees regarding this same topic as it impacts on reductions required in research project grants in order to fund a prescribed number of grants. Our advisory bodies have consistently felt that it is more prudent to fund high priority competing grants at levels closer to the peer reviewed recommended levels rather than provide less than optimal funding to individual awards. This question is relevant to the issue of centers funding as well. Dependent on the funds available and the input of our advisory bodies, the Institute will consider the best funding procedure to follow.

## BREAST CANCER

Question. Breast cancer is the second leading cause of cancer deaths among women in the U.S. According to NCI figures, breast cancer claimed 41,000 lives in 1987. About one in 10 American women will be stricken with this disease at some point in their lives. It is estimated that in 1988, 135,000 new cases of breast cancer will be diagnosed. Even more disturbing is that the incidence of this disease is rising; NCI has reported significant increases in both 1984 and 1985.

There has been considerable controversy surrounding one particular research study designed to determine if there is a link between dietary fat and breast cancer. Preliminary studies indicated that countries with low-fat diets had lower rates of breast cancer. In addition, women emigrating from low-fat diet countries to countries with higher fat consumption in the diet increased their risk of breast cancer. The controversial study would employ as many as 50,000 women whose diets would be monitored over a 10 year period. A study of this size could cost as much as $130 million over the 10 years.

What is the current status of the breast cancer study?

Answer. After considerable discussion with our advisory boards, including the National Cancer Advisory Board, it was determined that an orderly phase-out and termination of the Women's Health Trial was advisable. Subsequently, the NCI Executive Committee approved requests for a time extension and supplemental funding to provide for an orderly phase-out and termination of the Women's Health Trial.

Question. Is there any way to decrease the costs of such a study?

Answer. Randomized controlled trials can provide the best definitive tests for hypotheses suggested by epidemiologic and animal studies. The randomized controlled trial is a fundamental tool in the assessment of the efficacy of dietary intervention designed to reduce or prevent disease incidence.

A prevention trial is fundamentally different from the typical treatment trial in several respects. Prevention trials often require several clinical units to recruit sufficient numbers of subjects, and one or more coordinating units to standardize and facilitate their activities. A primary prevention trial requires the enrollment of healthy subjects and the disease endpoint occurs in a small portion of randomized subjects. Therefore, many subjects must be recruited, enrolled and followed for a number of years to achieve adequate statistical power. Motivation to alter dietary habits is often low in healthy subjects and can present difficulties with recruitment and compliance. The costs of the dietary intervention are not reimbursed by a third party and must be borne by the research project. Often, the nature of the dietary intervention precludes a double-blind design. Accordingly, analysis of the costs of a prevention trial does not always yield the results that would be anticipated from experience in treatment trials. Because prevention trials are often larger and more costly than treatment trials, their costs have received considerable attention. Models which have been developed to analyze costs in the context of clinical trial design have generally focused on therapeutic or treatment trials rather than prevention trials. Costs issues relevant to both treatment and prevention trials, such as the trade-off between sample size (number of subjects) and the length of follow-up needed for a trial, and the relative costs of accrual, intervention, and follow-up are addressed in these models.

A cost-analysis model was employed in estimating the cost of the Women's Health Trial (WHT). The model takes into account the relative costs of screening, recruitment strategies and follow-up, and the fixed and variable costs associated with each clinical unit in a multi-institution prevention trial, and costs associated with the two coordinating units.

The analysis of costs of the WHT suggested several ways to reduce costs in a prevention trial.

1) Use of the case-cohort approach can reduce costs substantially when the protocol includes collection of data or specimens which are costly to process.

2) Use of a smaller number of larger trial units offers important cost savings when establishing and maintaining a trial unit represents a significant portion of a trial unit's costs.

3) Use of recruitment strategies that allow trial units to maximize recruitment potential.

4) Use of high-risk subjects may not improve the efficiency of a prevention trial because restrictive eligibility requirements may reduce the recruitment potential. The favorable impact of high-risk subjects on sample size may fail to compensate for its costs in terms of additional clinical units.

Using the cost-analysis model to minimize overall costs, it has been estimated that the Women's Health Trial (WHT) as proposed would cost approximately $130 million (total costs) for a 10-year study with 32,000 women.

Efforts are being continued to find better ways to estimate the costs of a dietary intervention -- breast cancer prevention trial, particularly as a function of various trial design features so that 1) more precise estimates can be obtained, 2) costs can be reduced as much as possible within the constraints of trial protocol, and 3) ways to reduce costs by means of change in trial design features.

Question. The use of mammography in the screening asymptomatic women under the age of 50 for signs of breast cancer has been another source of controversy. A recent report in the Journal of the American Medical Association found that for very 10,000 women between 40 and 49 who have yearly mammograms for 10 years, only 22 lives would be saved at a cost of $350 million. The average cost of a mammogram in the U.S. is $100 and many health insurance plans do not reimburse. In 1977, NIH held a Consensus Development Conference on breast cancer screening which recommended mammography for women aged 40 to 49 only when there was a personal or family history of breast cancer. However, various medical professional groups have recommended mammography screening for women under 50, adding to the confusion. Is NIH and NCI planning another Consensus Conference on this matter?

Answer. The early results from the Institute funded Health Insurance Plan (HIP) study conducted in the 1960s utilizing existing mammographic technology, showed little benefit in screening asymptomatic women under age 50. However, after nine years of follow-up in the HIP study, there was evidence of benefit in women 40 to 49; at 18 years the benefit has been estimated at 20 to 30 percent. This same benefit resulted in the Breast Cancer Demonstration Detection Program (BCDDP) supported by the NCI in the 1970s using more advanced mammographic technology than was available in the HIP study. The ability to detect breast cancers was demonstrated to be virtually the same in women 40 to 49 as in women 50 to 59; and the results of 11 years follow-up on the BCDDP now have comparable survival rates, stage for stage between the two age groups.

In addition, in view of the improved mammographic technology and the long-term results of the HIP and BCDDP and upon the advice of consultants from a large number of Professional Medical Societies, the Division of Cancer Prevention and Control's Board of Scientific Counselors and the National Cancer Advisory Board, the NCI has adopted new "Working Guidelines for Breast Cancer Detection" which are:

- That physicians should encourage their female patients in doing monthly breast self examination. That physicians be encouraged to do clinical breast examinations on all female patients in whom they are doing a periodic examination.

- That beginning at the age of 40, a mammogram should be encouraged every one to two years until the age of 50 after which it should become annual.

- That in women with a personal history of breast cancer mammograms should be encouraged annually.

Based on the results of studies described and the consensus of the professional organizations and advisory bodies that contributed to the new guidelines, no additional NIH or NCI consensus development conference is planned.

Question. Is there another way to send a clearer message on mammography to the American public?

Answer. At present nearly all medical professional groups support the recommendations on mammography including the American Medical Association. NCI is actively working toward support by all medical professional groups to promote among their membership the value of using the consensus guidelines. Further, publication of these guidelines in professional medical journals also gets this information broadly distributed. Finally, the NCI is working with a number of state health departments to influence the use of early detection in their respective areas, including mammography.

## INTERLEUKIN-2

Question. In December 1985, there was extensive media coverage over a new experimental treatment involving the use of a natural substance, Interleukin-2 (IL-2), to stimulate the body's immune system against cancer. In December 1986 another report on the experimental IL-2 treatment was published along with an editorial challenging the work and severely criticizing the amount of attention the new treatment has received. Critics charged that the reports were premature, the treatment is very expensive, the side-effects too severe and the benefits are transient and uncertain. Most recently, the Washington Post (3/30/88) had an article indicating that a modification of the original treatment achieved dramatic success against skin cancer without as many severe side effects.

What is the current status of this new treatment?

Answer. The initial reports of Interleukin-2 treatment indicated substantial activity in renal cell carcinoma and melanoma. These diseases are refractory to treatment by any standard or investigational agent, with fewer than 15 to 20 percent of patients exhibiting any evidence of tumor regression to the most active agent or combination of agents. These regressions are typically of very short duration and of little benefit to the patient.

Studies performed within the Surgery Branch of the NCI demonstrated response rates of approximately 33 percent and 20 percent in renal cell carcinoma and melanoma, respectively. The six extramural centers, under contract to the NCI to perform Interleukin-2/lymphokine activated killer cells (IL-2/LAK) studies, produced response rates of 16 percent and 19 percent using an identical regimen in the same diseases. Modifications of this regimen were studied but did not produce superior response rates or significantly less toxicity.

A review of the responding patients in the extramural studies indicate that 15 to 25 participants achieving a response continue in complete or partial remission (range 9+ to 24+ months). Five of the six achieving complete response are still in remission greater than one year from the start of treatment. These data would indicate that although the overall percentage of patients achieving a remission is low, those achieving a response benefit from remissions which are durable. The toxicity induced by this regimen is substantial and requires intensive care unit (ICU) care during treatment, but in general has been completely reversible with a mortality rate of one percent.

Very few studies with mature data are presently available regarding the toxicity or efficacy of Interleukin-2 regimens without LAK cells. The contract institutions performed a trial of high dose IL-2 without LAK cells in melanoma. Although toxicity required ICU care, five responders were seen in 20 patients, with three complete remissions. Two are still without evidence of disease greater than 16 months from the start of treatment. Two recent reports indicate that lower dose regimens tolerated in the outpatient or non-ICU settings can produce responses in both renal cell carcinoma and melanoma. However the responses in these studies were of short duration, in contrast with responses seen in higher dose, more toxic regimens.

The contract institutions are pursuing the Surgery Branch IL-2/LAK schedule in studies of lymphoma and breast cancer. A separate study is in progress to identify any malignancies with a high degree of sensitivity to IL-2/LAK. Preliminary data indicated that substituting continuous infusion for bolus administration of IL-2 produced significant activity in patients with renal cell carcinoma (response rate 28 percent), therefore a study is in progress to compare bolus with continuous infusion IL-2 with LAK in this disease. Laboratory measures of immune activation accompany the latter study to identify correlates of response.

The development of IL-2 is proceeding with investigation of its administration by different routes (intraarterial, intrasplenic, intraperitoneal, brain intracavitary), in combination with other cytokines (interferons, TNF, and monoclonal antibodies), in combination with cytotoxic agents, in different schedules to increase efficacy and decrease toxicity, and as an adjuvant to active specific immunotherapy (tumor vaccine). Early data indicate that Interleukin-2 in combination with alpha-interferon, TNF, and cytotoxic agents respectively may be more active than the single agent alone, and activity may extend to other malignancies besides melanoma and renal cell carcinoma. In addition promising activity has been noted with IL-2 and TIL cells (a cell generated similar to LAK but found in tumors and with more potent tumor killing effects) in melanoma. Other methods of generating more potent and less toxic effector cells are currently under investigation through BRMP-funded contracts.

Question. What is the status of other immune system modulators, such as tumor necrosis factor and interferon, in the treatment of cancer?

Answer. There are a large number of cytokines and lymphokines that have been genetically cloned and are either currently in clinical testing or soon will be. These include several molecular forms of interferon, a variety of colony-stimulating factors (CSFs), interleukins numbered 1 through 6, tumor necrosis factor, transforming growth factors, and certain lytic effector molecules or perforins such as cytolysin. In addition, there are a large number of biological effector molecules that have not yet been cloned. These host-derived molecules are usually elicited in various combinations and in timed sequences in the tissues during a host antitumor response or a host inflammatory response. These molecules almost always work better in combination than alone. However, an ordered sequence of clinical development demands their initial use singly and then in combinations for which there are experimental data suggesting additive or synergistic activity. It should be apparent that the task of sorting out the most effective dose, route, and schedule is amplified by the very large number of agents and cells with which a particular agent might interact, and the development of these agents becomes even more complicated when additional treatment modalities like chemotherapy and radiation therapy are introduced. The earliest recombinant molecules to enter clinical trials, the interferons, are just beginning to be tested in combination with other treatment modalities. The progress has been slow but the potential is enormous.

Clinical investigations employing biological agents are complicated and must be undertaken painstakingly in order to gain the greatest possible information even from clinical trials in which tumor regressions are not frequent. A major goal for future studies is to develop methods to deliver the effector molecules to the sites of disease in an efficient manner. Such vehicles may include conjugation to antitumor antibodies or incorporation into liposomes directed to the tumor through the incorporation of antibodies into the outer lamellae.

## CANCER SCREENING

Question. In November 1984 researchers at Boston's Beth Israel Hospital reported the development of a new approach to the diagnosis of cancer. By employing nuclear magnetic resonance (NMR) technology, the scientists were able to distinguish cancer patients from patients with non-neoplastic disease or benign tumors as well as from normal persons. However, scientists from several research groups have been unable to confirm the NMR experiments.

What is the current status of this new approach to cancer diagnosis?

Answer. Dr. Fossel, who leads a group at Boston's Beth Israel Hospital, was the first to develop an innovative method to utilize water suppressed nuclear magnetic spectroscopy to measure an apparent serum marker of cancer. The initial studies, which were reported in the "New England Journal of Medicine," appeared to be promising and a number of other researchers are currently attempting to duplicate the research. Some investigators were initially unable to confirm the original observations; however, with help from the Beth Israel group, some laboratories have been able to obtain comparable results on duplicate samples. Other groups still have not been able to duplicate Dr. Fossel's results. Additional studies by Dr. Fossel and other investigators have suggested that the results may not be as generally applicable as was first thought. A major complication in the assay is that serum triglyceride levels can affect its outcome. Further research will be required to evaluate the utility and applicability of this test as a diagnostic method.

Question. What is the extent of the practical applications, and how far in the future?

Answer. It is too early in the development of this methodology to predict the extent of practical applications. The NCI is currently exploring a number of approaches to answering these questions. Additional investigators are being supported to pursue studies both to evaluate the applicability of the assay and to identify the marker that is being measured. In addition, the NCI is in the process of designing a clinical study to evaluate whether this assay is useful as an adjunct to diagnosis in defined settings. These studies are expected to take two to three years to complete. In the meantime, the NCI will continue to monitor progress being made by the Beth Israel group and others and will assist the efforts to evaluate this methodology.

## PROGRESS IN CANCER RESEARCH

Question. Although there have been advances in curing certain cancers (Hodgkin's disease, and childhood cancers), the number of people who have benefitted from these treatments are small when compared with those affected by the more common cancers (lung, colon, and breast), which have not experienced similar improvements in cure rates. NCI emphasizes the five year overall survival rate which has improved slightly from 47 percent to 49 percent between 1973 and 1983. However, critics charge that survival data are subject to substantial bias from changing standards of diagnosis and reporting. For example, early detection of cancer through programs may only be producing a lead time, causing longer morbidity and apparent survival times. In addition, due to the increased use of microscopic tissue diagnosis, tumors are found that have the appearance of cancer but not its biological behavior. Thus, some "cured cancers" may not actually been cancer in the first place. Critics also point to mortality rates which, when adjusted for changes in age distributions and population size, have increased by 8.7 percent from 1962 and 1982. NCI has received considerable criticism on this issue, most recently in a March 1987 GAO report. A change in emphasis from treatment research to prevention is often suggested.

What is NCI's response to charges on the lack of progress against cancer?

Answer. Indeed, much has been written and discussed over the past several years over the question of the extent of progress against cancer. Mortality statistics have been cited to argue that progress has been slow and that any reductions in mortality have been only for the low incidence cancers. Some have called the survival figures into question as measures of progress against cancer based on statistical grounds.

Yet, the facts on progress are quite clear. Table 1 shows that age-specific mortality rates have declined for all ages up to 55 for all cancers; and up to age 85 for cancers grouped together without lung cancer. The fact is that the risk of dying from any cancer other than lung cancer has decreased for almost all Americans, except that group 85 years of age and older.

Table 1 also shows that in every age group under age 55 in which a decrease has occurred, except for ages 35 to 44 with lung cancer excluded, the average annual decrease has been greater in the most recent time period. This is indicative of recent advances in progress. On the other hand, the average annual changes in ages 55 and over represent an increase in mortality and have been greater during the most recent time period. We believe that in part this increase may be the result of increased survival among the younger age group, with patients actually living longer but still dying from cancer. In any case, the overall prognosis is improved for the majority of Americans. This is particularly true for those who do not smoke, since smoking is responsible for some 80 to 85 percent of lung cancer.

When the age-specific figures are aggregated into an overall index by weighing each rate with the percentage of the population in each age group in a base or index year (1970 is the year we generally use) we have another measure of change in cancer. This measure, the age-adjusted mortality rate, is given on the last line of Table 1 and shows that for all cancers combined the mortality rate has risen over the past 35 years by 9.1 percent, but that the driving force behind that increase has been lung cancer. If we temporarily remove lung cancer from the picture, mortality from cancer has actually fallen by 13.3 percent.

Age-specific and age-aggregated trends still do not give a full picture of cancer. It is essential that individual cancer sites be examined. Table 2 gives an overview of the 35-year changes for a number of specific cancer sites utilizing the three major cancer measures, mortality, incidence and survival.

Perhaps the most striking aspect of these trends is the extent to which mortality has decreased. The mortality from childhood cancers (down 56 percent), Hodgkin's disease (down 61 percent), testicular cancer (down 60 percent), colorectal cancer (down 20 percent), bladder cancer (down 33 percent), cervical cancer (down 73 percent), laryngeal cancer (down 12 percent), and corpus uterine cancer (down 60 percent) all have shown significant declines due to improvements in treatment and diagnosis. In addition, mortality from melanoma has not risen as rapidly as incidence; nor has mortality from kidney cancer risen as rapidly as incidence.

Clearly, any charges of lack of progress are not compatible with the data that exists today regarding the progress against cancer. Advances have been startling on the developmental side of cancer research where the results of basic research are being brought into the clinic in the form of new therapies. We now have available treatments, that within the study population, can reduce mortality for every single one of the major cancer killers. None existed before the 1971 cancer initiative. This has come about predominately due to the cascade of knowledge concerning basic research on cancer that has surfaced in recent years.

However, not all the results of research are being applied in general practice. The reasons for this are more socioeconomic than scientific. As an example, at the present time only 20 percent of women who we think should receive a mammogram, actually receive one. Yet, if every woman over the age of 50 in the U.S. had an annual mammogram, the mortality from breast cancer would decline by 30 percent or at least 15,000 lives a year.

With respect to treatment, data indicate that only about 20 percent of women eligible for breast sparing surgery are receiving this treatment even though the clinical studies show that survival is equivalent between the methods. The reasons for this incomplete transfer of proven technology are not fully understood, but we are attempting, through our cancer control efforts, to achieve full use of our knowledge.

Now, let me turn to the various so-called biases that are associated with cancer survival data. We are fully aware of the potential for such biases and for this reason we examine our data carefully to determine whether those biases may be present for specific cancers; we publish suggestions on how to interpret the data to make readers aware of these potential problems; but most importantly we combine the survival data with other data to produce as complete a picture of the impact of cancer as possible.

This strategy is entirely consistent with the recommendations contained within the report requested by this Committee during last year's budget cycle. This report which assessed the measures of progress against cancer was prepared by a panel of extramural experts, and is currently underlying Departmental clearance.

Finally, when we speak of progress against cancer it is essential to again realize that our knowledge of cancer biology is vastly different from that at the beginning of the National Cancer Program in 1971. This new knowledge will be crucial to future progress. We will continue to track in detail our progress against cancer to provide the information that will guide our efforts in basic research, cancer prevention and control, and application programs.

I would like to present for the Committee's review a summary of the recent trends for the cancers outlined in Table 2:

- Lung cancer: The incidence of lung cancer, the leading cause of cancer deaths, decreased among both white and black males in 1985. Among white males, lung cancer incidence decreased from the 1984 figure of 84.0 cases per 100,000 males to a rate of 80.5 in 1985. The 1985 figure is the lowest since 1977 when the rate was 80.0. In general, there appears to be a leveling off of the rate of lung cancer mortality in males.

  The trend for lung cancer morbidity in females has been increasing when assessed as an overall age-adjusted rate, although the trend among young women (under 45) has been decreasing. Another sign of a reduction in this disease is that there has been only a 1.1 percent increase in mortality between 1983 and 1984 and 1984 and 1985, the lowest in many years, and the overall incidence rate has been essentially level since 1983.

  The decrease in the rate of change of both incidence and mortality for lung cancer is consistent with the reduced percentage of Americans who smoke.

- Breast cancer: The significant progress in treatment (which shows achievable reductions in mortality in Stage II disease from 18 percent [postmenopausal women] to 36 percent [premenopausal women]) and in screening which shows that a 30 percent reduction in mortality can be achieved are not reflected in the mortality or the screening statistics. It is one of the primary challenges in cancer control to bring these technologies to bear in full measure on the breast cancer problem. Breast cancer is second only to lung cancer in the loss of years of life.

  Breast cancer mortality has remained essentially level among white females and increased about one percent per year among black females during the 13-year period, 1973 through 1985. Analysis by age group shows that women under 50 experienced a distinct decline in mortality up through 1983; but in 1984 there was an increase in mortality followed by another small increase in 1985. The pattern for women over 50 has been essentially one of no change through 1979, after which each succeeding year shows a small increase. The reasons for these changes are not clear. For example, the decrease in mortality resulting from improvements in survival afforded by treatment might be offset by increases in incidence. However, the lack of a large decline in mortality is strong evidence that little effective screening is taking place because clinical trials have shown that early detection through mammography and physical examination with appropriate follow-up can reduce the mortality rate from this disease by over 30 percent.

- Colon and rectal cancer mortality continues to decline in the face of increasing incidence, and figures on survival show that five-year survival is increasing. The changes in mortality and survival are consistent with both better management and earlier detection. Yet recent figures show that some 20 percent of the cases are discovered in the so-called distant stage which has a five-year relative survival of only six percent compared with 85 percent for cancers detected at the earliest stage (local disease) and 55 percent for cancers that have already incurred some spread to a nearby region (regional disease).

- The decrease in testicular cancer mortality for 1950 through 1985 (60.0 percent) is all the greater when the increase in incidence (85.1 percent) is taken into account. The decrease in mortality is directly attributable to improved treatment.

- The increase in incidence in cancer of the prostate gland (68.7 percent over 35 years) is coupled with a small increase in mortality (5.7 percent). The recent changes indicate that these figures contrast with previous figures for the 10-year period 1973 through 1982 in which the incidence increased by 26.4 percent compared with 7.2 percent for mortality. It would seem, therefore, the steep rise in prostate incidence from the early 1970s is abating. In addition, the relatively constant nature of mortality indicates that a portion of these excess cases will not lead to death, either because of the nature of the disease or the age of the affected patient.

- The decline in Hodgkin's disease mortality (61.0 percent over 35 years) compared with an increase of 23.9 percent in incidence over the same period is consistent with the improvements in treatment that emerged from research over the past 15 to 20 years.

- There has been a marked increase in the incidence of cancer diseases known as non-Hodgkin's lymphoma (123.1 percent over 35 years with 26,500 new cases in 1985), and an increase in mortality (100.3 percent) which lags slightly behind the increase in incidence. A definitive reason for the increases is not known, but is under investigation.

- The past 35 years have seen the incidence and mortality rates for cancer of the cervix fall more than 70 percent, and this cancer has become one of the most preventable and curable cancers when detected in an early stage. The five-year relative survival rate for all stages combined was 67 percent for cases diagnosed during 1979 to 1984 while the survival rate for cases with localized disease was almost 90 percent. Yet not all women are screened and the mortality from this disease is larger in some areas of the country than others.

- Stomach cancer is the ninth leading cause of cancer mortality accounting for an estimated 24,700 cases and 13,949 deaths in 1985. Both the incidence and mortality rates have been falling, although the rate of decrease in both rates has declined in recent years. Survival from stomach cancer is about 16 percent; however, survival from local stage disease is about 57 percent, an increase from about 42 percent in 1950 through 1954. Improvements in diet and advances in diagnostics are the most likely factors causing the changes.

- Cancer among children under the age of 15 account for 6,000 new cases of cancer per year or less than one percent of all cancers. However, in terms of premature death, childhood cancers represent the largest life lost from cancer burden with an average of 65 years of life lost per child dying from cancer. In 1985, there were 1,840 cancer deaths among children. Over the time period 1950 through 1985, the incidence of childhood cancers increased by 13 percent while mortality decreased by 56 percent. The dramatic decrease in mortality during this time period is due entirely to the major advances made in successfully treating many forms of childhood cancers.

- Cancer of the uterine corpus is the most common of the gynecologic tumors accounting for about 37,000 new cases every year and 5,959 deaths. This disease also has the most favorable prognosis of the gynecologic cancers with a five-year relative survival rate of over 80 percent for all stages combined and over 90 percent for those women diagnosed with their cancer in a localized stage. Mortality for this disease has been steadily decreasing amounting to a 60 percent decline over 35 years due to improved treatment, most likely the extensive use of radiation therapy.

- The incidence of bladder cancer, the fourth most frequently occurring cancer among men, has increased by over 50 percent since 1950. This trend has been tempered by advances in treatment to yield a 33 percent reduction in mortality. The incidence may be due in part to increased detection of in situ cancers to maintain consistency in looking at trend data in the context of diagnostic and coding changes which have occurred since the early 1970s. The detection, treatment, and survival reflect the full range of improvements in cancer care which have emerged over the past three decades.

- Incidence of cancers of the kidney and renal pelvis has increased by 82 percent over the period 1950 to 1985, mortality has increased by only 23 percent. The relative improvement in mortality appears to be due to improved treatment; the reasons behind the increase in incidence are thought to be cigarette smoking and obesity, although the specific factors responsible are not known.

- Five-year relative survival for leukemias as a group is currently 32 percent with rates of 48 percent and 60 percent for acute and chronic lymphocytic leukemias, respectively, and seven percent and 22 percent for acute and chronic myeloid leukemias, respectively. Over the time period 1950 through 1985, incidence increased sharply between 1950 and 1975 then decreased between 1975 and 1985. On the other hand, mortality increased only slightly between 1950 and 1975 and then declined. The almost steady mortality rates in the face of increasing incidence rates are due to advances in treatment over the time period.

- There are approximately 22,000 new cases of malignant melanoma of the skin diagnosed annually and 5,529 deaths from the disease. The long term trend in this disease shows more than a 242 percent increase in incidence over the past 35 years with almost a 150 percent increase in mortality. The changes reflect significantly increased risks, probably due to lifestyle changes resulting in increased exposure to sunlight.

- Deaths from ovarian cancer were estimated to be 11,700 in 1987. The trend in incidence has not shown much change in the past 35 years. Mortality has shown an increase followed by a nine percent decrease so that current rates approximate those of 1950. The observed increase in survival rates may be due in part to an increase in the proportion of women receiving chemotherapy.

## Table 1

### 35-Year Trends in Cancer Mortality

Rates per 100,000 Persons,
All Races, Both Sexes

| | | | | Percent Change | | |
|---|---|---|---|---|---|---|
| Age Group | All Sites Without Lung | | | Average Annual | | Total |
| (Years) | 1950 | 1975 | 1985 | 1950-75 | 1975-85 | 1950-85 |
| 0 - 4 | 10.9 | 5.2 | 3.6 | -2.1 | -3.1 | -67.0 |
| 5 -14 | 6.5 | 4.7 | 3.5 | -1.1 | -2.6 | -46.2 |
| 15 -24 | 8.3 | 6.5 | 5.3 | -0.8 | -1.9 | -36.1 |
| 25 -34 | 18.9 | 13.9 | 12.2 | -1.1 | -1.2 | -35.4 |
| 35 -44 | 59.3 | 43.2 | 39.8 | -1.1 | -0.8 | -32.9 |
| 45 -54 | 154.4 | 130.2 | 118.9 | -0.6 | -0.9 | -23.0 |
| 55 -64 | 343.1 | 300.4 | 292.2 | -0.5 | -0.3 | -14.8 |
| 65 -74 | 636.1 | 575.5 | 586.0 | -0.4 | 0.2 | -7.9 |
| 75 -84 | 1092.4 | 964.4 | 1004.2 | -0.5 | 0.4 | -8.1 |
| 85 and over | 1401.9 | 1303.0 | 1403.5 | -0.3 | 0.8 | 0.1 |
| All ages | 144.0 | 125.4 | 125.0 | -0.5 | -0.0 | -13.3 |

| | | | | Percent Change | | |
|---|---|---|---|---|---|---|
| Age Group | All Sites | | | Average Annual | | Total |
| (Years) | 1950 | 1975 | 1985 | 1950-75 | 1975-85 | 1950-85 |
| 0 - 4 | 11.0 | 5.2 | 3.6 | -2.1 | -3.1 | -67.3 |
| 5 -14 | 6.6 | 4.7 | 3.5 | -1.1 | -2.6 | -47.0 |
| 15 -24 | 8.5 | 6.6 | 5.3 | -0.9 | -2.0 | -37.6 |
| 25 -34 | 19.6 | 14.6 | 12.8 | -1.0 | -1.3 | -34.7 |
| 35 -44 | 63.9 | 53.9 | 48.2 | -0.6 | -1.1 | -24.6 |
| 45 -54 | 174.7 | 179.2 | 169.3 | 0.1 | -0.5 | -3.1 |
| 55 -64 | 392.0 | 423.2 | 441.3 | 0.3 | 0.4 | 12.6 |
| 65 -74 | 695.0 | 769.7 | 848.0 | 0.4 | 1.0 | 22.0 |
| 75 -84 | 1147.5 | 1155.8 | 1290.2 | 0.0 | 1.2 | 12.4 |
| 85 and over | 1444.8 | 1437.6 | 1596.2 | 0.0 | 1.1 | 10.5 |
| All ages | 157.0 | 162.2 | 171.3 | 0.1 | 0.6 | 9.1 |

## Table 2

## Site-specific Trends: 1950 to 1985

Males and Females

|  |  |  | Whites |  |  |  |  |  |  |  |
|---|---|---|---|---|---|---|---|---|---|---|
|  | All Races |  | Incidence |  |  | Mortality |  |  | 5-Yr Survival |  |
| Site | Cases 1985 | Deaths 1985 | 1950 | 1985 | Percent Change | 1950 | 1985 | Percent Change | 50-54 | 79-84 |
| Stomach | 24,700 | 13,949 | 26.6 | 7.3 | -72.5 | 18.4 | 4.6 | -74.8 | 12.0 | 15.7 |
| Cervix | 15,000 | 4,508 | 32.6 | 7.3 | -77.5 | 9.9 | 2.7 | -73.0 | 59.0 | 66.7 |
| Melanoma | 22,000 | 5,529 | 2.9 | 9.8 | 242.3 | 0.9 | 2.3 | 147.9 | 49.0 | 80.3 |
| Lung-Males | 98,000 | 83,754 | 27.4 | 85.6 | 212.8 | 22.0 | 72.2 | 228.4 | 5.0 | 11.6 |
| Lung-Females | 46,000 | 38,641 | 6.8 | 36.3 | 432.4 | 4.9 | 26.8 | 447.2 | 9.0 | 15.5 |
| Non-Hodgkin's Lymphoma | 26,500 | 15,358 | 5.9 | 13.1 | 123.1 | 2.9 | 5.9 | 100.3 | 28.0 | 49.4 |
| Testis | 5,000 | 425 | 2.4 | 4.5 | 85.1 | 0.8 | 0.3 | -60.0 | 57.0 | 90.5 |
| Kidney | 19,700 | 8,660 | 4.3 | 7.8 | 82.1 | 2.7 | 3.3 | 23.1 | 34.0 | 51.2 |
| Larnyx | 11,500 | 3,501 | 3.0 | 5.1 | 68.9 | 1.4 | 1.2 | -12.2 | 52.0 | 66.0 |
| Prostate | 86,000 | 25,940 | 45.3 | 76.4 | 68.7 | 20.4 | 21.5 | 5.7 | 43.0 | 72.7 |
| Bladder | 40,000 | 9,785 | 12.2 | 18.4 | 51.1 | 5.1 | 3.4 | -32.7 | 53.0 | 76.7 |
| Breast-Females | 119,000 | 40,090 | 74.4 | 107.0 | 43.6 | 26.4 | 27.6 | 4.4 | 60.0 | 75.0 |
| Childhood Cancers | 6,000 | 1,840 | 10.9 | 14.3 | 13.0 | 8.2 | 3.6 | -55.9 | 30.0 | 63.1 |
| Hodgkin's Disease | 6,900 | 1,778 | 2.8 | 3.4 | 23.9 | 1.7 | 0.7 | -61.0 | 30.0 | 73.8 |
| Colon\ Rectum | 138,000 | 57,586 | 45.8 | 54.4 | 18.6 | 25.7 | 20.5 | -20.3 | 42.0 | 53.3 |
| Corpus Uteri | 37,000 | 5,959 | 23.2 | 23.7 | 2.3 | 8.9 | 3.6 | -60.0 | 72.0 | 83.3 |
| Leukemia | 24,600 | 17,449 | 9.5 | 9.6 | 0.8 | 6.4 | 6.6 | 2.2 | 10.0 | 32.1 |
| Ovary | 18,500 | 11,357 | 14.6 | 14.7 | 0.2 | 7.9 | 7.9 | -0.4 | 30.0 | 37.3 |

Question. Will NCI be increasing the amount of research on cancer prevention?

Answer. The National Cancer Institute plans to increase its prevention research from an estimated level of $431.5 million in FY 1988 to $485.4 in FY 1989.

## LUNG CANCER VACCINE

In initial clinical trials an experimental anticancer vaccine, developed by researchers at George Washington University, doubled survival rate of early stage lung cancer patients. Although it is not a vaccine in the classic sense since it does not prevent disease, it helps the patient fight existing disease by increasing the immune system response. The vaccine increased five-year survival rates to between 53 and 75 percent, depending on how the treatment was given after surgery, compared with 33 percent of those just treated with surgery. By monitoring the patient's response to the vaccine treatments, the researchers were able to predict which patients will do well on the regimen.

Question. What is the current status of this new form of treatment?

Answer. Successful treatment of cancer patients with tumor vaccines requires a very specific immune response to the vaccine which cross-reacts with tumor cells elsewhere in the body. Since the specificity of this response is key, preparation and administration of the vaccine must be carefully controlled. In the study referenced, patients treated at some of the institutions apparently did not have the appropriate immune response so additional work will need to be done before widespread application of this approach is possible. Despite this complication, the NCI is actively pursuing this promising area of research.

Question. Is this form of treatment applicable to other types of cancer?

Answer. Clinical trials are being conducted to identify promising tumor vaccines for other malignancies, such as colorectal carcinoma and malignant melanoma. Preliminary laboratory data also suggest that the administration of immune stimulants, such as Interleukin-2 or Interferon gamma, after the vaccination procedure may increase the patient's antitumor response.

## CERVICAL CANCER

Question. It has been widely reported over the past year that the Pap smear, one of the most common laboratory tests in the U.S., is also one of the most inaccurate. It is estimated that the test, as it is currently being performed, fails to detect roughly one in four cases of cervical cancer. Lab technicians are overworked, undersupervised and poorly paid. An estimated 60,000 women in the U.S. are expected to develop cancer of the cervix in 1988. If detected early, the disease is almost always curable, but approximately 7,000 American women die of the disease each year. Another factor increasing the alarm is that some doctors now believe cervical cancer develops faster than previously thought. In addition, the rate of cervical cancer seems to be increasing in young women.

Complicating the issue is the recommendation by the American Cancer Society that women age 20 to 40 need a Pap test only every three years after two consecutive negative annual tests. Since its release in 1980, the triennial screening guidelines has been a source of growing controversy. A March 1988 conference in Atlanta was held in response to the recent media reports on the accuracy of the Pap test. The conference was sponsored by NCI along with the Centers for Disease Control and the Health Care Financing Administration.

What is NCI's current position/recommendation on how frequently women should have a Pap test?

Answer. In August 1987, a conference with representatives of nearly all medical professional organizations was held in Annapolis, Maryland to consider the above question -- a consensus was developed and a joint recommendation made which all organizations have taken back to their boards for endorsement.

On September 30, 1987 the National Cancer Advisory Board accepted the "Working Guideline on the Early Detection of Cervical Cancer", "That all women who are, or have been sexually active, or have reached age 18 years, have an annual Pap test and pelvic examination. After a women has had three or more consecutive satisfactory normal annual examinations, the Pap test may be performed less frequently at the discretion of her physician."

In January 1988 a press release was made by the American Cancer Society, the American Medical Association, the American College of Obstetrics and Gynecology and the National Cancer Institute announcing the joint endorsement of this guideline. Nearly all other organizations have endorsed it or are in the process of endorsing the guidelines.

Question. Is NCI involved in trying to improve current laboratory failure rate with the Pap test?

Answer. Immediately upon release of the Wall Street Journal article on problems with the quality of Pap tests, NCI participated in meetings with representatives of the College of American Pathologists, American College of Obstetrics and Gynecology, American Cancer Society, the Center for Disease Control (CDC), and the Health Care Financing Administration (HCFA), which has as its mandate the control of laboratories. A joint meeting was held March 4th in Atlanta between the CDC, HCFA and the NCI to consider this matter.

Question. What were the results of the 1988 conference in Atlanta on the Pap test?

**Answer. The objectives of the conference were to discuss the status of the Pap smear testing, to identify aspects which need to be improved, to discuss the essential features of within-lab quality assurance, to discuss external monitoring of lab performance, and to provide a forum for the many organizations and institutions to present current and future programs.**

**In the introductory remarks, it was made clear that the purpose of the conference was not to arrive at a consensus. Rather the discussions were to be free flowing. The next conference has been scheduled for August 1988, at which time a consensus will be reached.**

## AIDS RESEARCH

Question. NIAID is requesting an increase in AIDS research funds from $223,383,000 in FY 1988 to $310,268,000 in FY 1989. NIAID's FY 1989 AIDS research budget is 53 percent of the total NIH research budget on AIDS. In FY 1988, NIAID's portion was 59 percent of the NIH AIDS budget; in FY 1987, 58 percent; in FY 1986, 47 percent; and in FY 1985, 37 percent. Approximately 42 percent of NIAID's total budget is spent on AIDS research. Since NIAID spends a large percentage of its budget on AIDS research, has it been necessary to cut back on other areas of research?

Answer. The NIAID is no longer redirecting any additional funding or staff from other program areas to support AIDS efforts.

Question. Has NIAID primarily made use of these budget increases by increasing the number of basic research grants, or through the expansion of clinical trials on drugs to combat AIDS, or other programs?

Answer. There are a number of new areas of research we expect to begin as well as others that we will be expanding. These include drug development, clinical trials, vaccine development, and preparing for the next phases of vaccine evaluation. In addition, we will increase our emphasis on basic biomedical research, largely supported through research project grants. During the early stages of NIAID involvement in AIDS, the need for applied research using contracts far exceeded grants. This has changed and the balance has shifted toward grants.

Question. Last year's "Justification" document briefly mentioned that NIAID intended to "establish a national network for multidisciplinary Centers for Excellence in Basic AIDS Research." What is the current status of these new centers?

Answer. The NIAID believes that vigorous support of multidisciplinary basic research efforts led by the very best of our scientists is essential to ultimate control of HIV infection. To this end, the NIAID established the Program of Excellence for Basic Research in AIDS (PEBRA) initiative to support integrated basic research programs addressing questions on the pathogenesis of HIV infection and its complications. Leading researchers in the fields of cellular and molecular biology, immunology and virology have been encouraged to apply for these investigator-initiated program project research grants.

Question. How many were planned and what percentage are now functioning?

Answer. The NIAID has received 26 PEBRA applications that will be reviewed in June 1988. The Institute has set aside $14.4 million for the first year funding of the PEBRAs and plans to make between 6 to 8 awards in September 1988. The PEBRAs will be funded for up to a five year period.

## PROCESSING OF AIDS GRANT APPLICATIONS

Question. In response to the potential passage of S-1220, The AIDS Research Information and Care Act, NIH's Division of Research Grants has prepared "ASAP," Accelerated Solicitation to Award Process. ASAP will cut the amount of time necessary to process an AIDS grant application from 12 months down to 6 months. How will NIAID be affected by this new program provided the legislation becomes law?

Answer. ASAP, Accelerated Solicitation to Award Process, which reduces the amount of processing time from 10-12 months to six months, is possible with regular research grants if accompanied by an increase of staff and necessary equipment. ASAP time requirements have been decidedly more difficult to accommodate with large program project and center grant applications, the only types of applications solicited by NIAID in 1988.

This past Council round alone, there were a total of 115 large applications to be reviewed by NIAID in response to four RFAs; when two unsolicited program projects and two large supplemental applications were added, the total, 119 large, complex applications, translates to a significant workload and the dramatic need for additional staff. Another factor compounding the problem is the growing reluctance of reviewers, busy with their own research and academic responsibilities, to invest the amount of time and effort that ASAP requires.

While some of these problems will undoubtedly be resolved in time, it is becoming evident that a seven to eight-month period appears to be more realistic for large applications and proposals. In earlier memos, we pleaded for an extension of the processing of large grant applications to 8 months, which would considerably expedite the process but would maintain orderliness and thoroughness of review. To drastically expedite a process periodically because of exceptional cases is one thing, but the implementation of ASAP as a continuing process may be counterproductive and may, in fact, result in rapid burnout of people crucial to the process, (i.e., review staff executive secretaries, grants management staff, and peer reviewers). Extension of the present 6-month ASAP requirement to 7 or 8 months, particularly for large grant mechanisms, may be more reasonable and easier to accommodate.

## AIDS VACCINE

Question. At this writing, at least two AIDS vaccines have been approved for clinical trials. Several others are awaiting FDA approval. The first approved vaccine against AIDS, developed by

MicroGeneSys along with NIH is having difficulty in finding enough suitable volunteers. Many male homosexuals are reluctant to volunteer because following injection of the vaccine, their blood would test positive for HIV when tested with an ELISA test. Others have dropped out of the trial because of the time commitments required, or were rejected for medical reasons, like hypertension. The number of homosexual males in the U.S. will not be large enough to support the widespread testing of multiple vaccines. Has NIAID begun to address the basic problems of finding enough suitable and willing volunteers needed to test the AIDS vaccine in this country?

Answer. In order to expedite AIDS vaccine evaluation, the NIAID has supplemented its six existing Vaccine Evaluation Units to carry out Phase I and Phase II trials of candidate vaccines. The Units have vast experience in the evaluation of other viral vaccines, and are presently carrying out a trial of the first candidate AIDS vaccine to be approved for testing by the FDA. An extensive information campaign was developed surrounding this first trial, and all of the subjects required for evaluation of the vaccine in Phase I have been entered into the study. In order to guarantee that enough volunteers will be available for testing other vaccines as they become approved by the FDA, NIAID is planning to expand its information campaign regarding AIDS vaccine trials, particularly as the trials expand from Phase I to Phase II, where greater numbers of individuals at high risk for HIV infection would be needed. Moreover, the number of Vaccine Evaluation Units may also be expanded to accomplish these needs.

Question. Will it be necessary to test vaccines in other countries?

Answer. Phase III efficacy trials of candidate AIDS vaccines will be carried out in large populations where the incidence of HIV infection is great enough to determine efficacy in a placebo-controlled trial. Several potential populations in the United States may be applicable, including homosexual men, intravenous drug users, prostitutes, and spouses of hemophiliacs. However, concerns raised regarding declining rates of infection in homosexual men, innovative approaches necessary for long-term follow-up of intravenous drug users and prostitutes, and the limited numbers of spouses of hemophiliacs suggests that Phase III trials may also have to be carried out in other countries. Collaborative efforts have been initiated to strengthen the clinical epidemiology databases, virology and immunology infrastructure, and laboratory training in nations where Phase III trials could be carried out based on incidence of HIV infection.

## _HAEMOPHILUS_ _INFLUENZAE_ VACCINE

Question. _Haemophilus_ _influenzae_ causes severe meningitis in children under 18 months of age. The infection is difficult to treat, and has a 5-15 percent mortality rate in the U.S. The FY 1989 Justifications document indicates that NIAID is supporting a clinical trial of a new vaccine. What is the status of the _H. influenzae_ vaccine?

Answer. The NIAID has an ongoing contract-supported study conducted by the University of California, Los Angeles, among Alaskan natives. This double-blind, placebo-controlled, randomized efficacy trial was begun in Alaska in December 1984 to test a new Haemophilus influenzae type b (Hib) protein-polysaccharide conjugate vaccine in a high-risk population of native infants. The vaccine or placebo control was administered as part of a primary immunization series at 2, 4, and 6 months of age simultaneously with DTP vaccine. The study is designed to assess the protective efficacy of the vaccine in reducing the incidence of invasive Hib disease.

Recruitment into the trial was discontinued as of January 1988, after 2,113 subjects had been enrolled. No significant differences have been observed in the reported rates of local and systemic reactions between the vaccine and placebo groups. In addition, no adverse effects have been associated with vaccine administration. Efficacy and other data from the trial should be available by September 1988 and will include three years of recruitment and one year of follow-up studies. It is hoped that an effective vaccine for the prevention of Hib infections in infants will be available by 1990 to become part of the routine well-baby care vaccination schedule.

## PERTUSSIS VACCINE

Question. According to last year's Justification document, NIAID had developed a genetically engineered pertussis vaccine which was being tested in animals. What is the status of these animal experiments? How soon will the vaccine be tested in humans?

Answer. The major thrust of Dr. Jerry Keith's effort at NIAID's Rocky Mountain Laboratories has been to produce recombinant subunit preparations of pertussis toxin that may be used as an acellular vaccine candidate. Pertussis toxin is an extracellular protein composed of 5 dissimilar subunits termed S-1 through S-5. Mice immunized and boosted with either the S-1 or S-2 recombinant subunit preparations produced increased amounts of anti-pertussis toxin antibodies. Despite these increases, none of the S-1 or S-2 immunized mice was protected, as judged by survival, from intracranial challenge (IC) with Bordetella pertussis. However, co-administration of subimmunogenic doses of active pertussis toxin potentiated the protective capability of the isolated S-1 recombinant subunit. It, therefore, appears that small amounts of toxin may be necessary to provide an immunogenic form of the S-1 subunit when using an IC challenge animal model. Furthermore, the addition of the S-2 through S-5 subunits also restores biologic activity and provides protection in the IC challenge model. The mechanism mediating these activities is now being investigated. Additional studies on both the structure-function relationship and protective activities of recombinant subunits must be completed before human trials with these preparations get underway. A timeframe of at least 1 to 2 years is expected to complete these studies.

Question. Are there indications that the new vaccine will be less likely to produce the undesirable side effects that are associated with the current pertussis vaccines?

Answer. There is a strong likelihood that the use of any acellular or subunit pertussis vaccine will significantly diminish the occurrence of the more common, less severe adverse reactions in infants generally seen with whole cell vaccine. These reactions include redness and swelling at the site of injection, and fever, drowsiness, and persistent crying within the first 48 hours following immunization. Most of these immediate systemic effects have generally been ascribed to endotoxin. Maximum efforts have been made to remove most, if not all, endotoxin from all acellular pertussis vaccine preparations.

Phase I trials in infants receiving these vaccines indicate that fewer common reactions are noted compared to infants receiving whole cell pertussis vaccine. The current whole cell vaccine has been associated with other, more severe reactions. It is thought that the acellular vaccines will also be less likely to be associated with these rare events, but this will only be determined after the acellular vaccines have been licensed and in use.

## DENTAL TRAINING AND PRACTICE ISSUES

Question. According to your testimony, the Nation's dental health is improving rapidly, particularly in the younger generation. It seems reasonable for us to suppose that the demand for dental practitioners might decrease over the next decade. This trend appears already to be underway as reflected by decreases in dental school enrollment, according to some sources. What is the present status of enrollment in the nation's dental training facilities?

Answer. In 1987, first year enrollment in U.S. dental schools was 4,370. The total enrollment for all years of training was 17,885.

Question. Is it increasing or decreasing?

Answer. Since 1978, first year enrollment in U.S. dental schools has declined by 30.6 percent. Since 1980, total dental school enrollments have decreased by 21.7 percent.

Question. What major changes do you see occurring in the nation's dental practitioner community over the next decade as the Nation's dental health improves?

Answer. The declining caries rate found in recent epidemiological studies will result in more people retaining their teeth for longer periods of time. As a result, we can expect an increased demand for services of a wider variety than at present. The services will include such problems as root caries, which primarily occurs in older-aged groups, increased wear and abrasion of teeth, periodontal diseases, and various types of oral soft tissue lesions more commonly seen in later years. More extensive knowledge and sophisticated diagnostic skills will be required to provide increasingly complex services to patients in private practice as well as to such special patient populations as the medically compromised, the handicapped, and those with AIDS.

## ELIMINATION OF TOOTH LOSS IN THE ADULT AND ELDERLY

Question. In the Justification (p. 218-219), you state that the Institute has assembled an expert Ad Hoc working group to assist in the development of a comprehensive oral health program for adult and older Americans etc. How is this program developing and how will it work?

Answer. Following a second meeting of the Ad Hoc Senior Dental Advisors in December 1987, three groups of expert scientists met in February, 1988, to discuss dental caries, periodontal diseases and self-care/professional utilization in relation to tooth loss. Their discussions and research recommendations are under review by the Senior Dental Advisors and will guide formulation of an action plan which will be presented later this year. Simultaneously, senior staff have been meeting with professional associations and other government agencies to inform them of the initiative and elicit their cooperation in coordinating research efforts.

In addition, the NIDR has undertaken an inventory of some 300 national and state organizations to assess the availability of oral health education and oral health promotion activities for adults. The results of this inventory will be helpful in coordinating research and building a coalition, as well as providing state-of-the-art information on oral health activities for the nation's adults.

The oral health program is expected to begin on a project-by-project basis with the unifying theme of reducing toothlessness. Some efforts will be directed toward demonstration research programs which test effectiveness and efficiency of strategies to reach adults with appropriate oral disease prevention methods. Both NIDR and interagency initiatives, e.g., joint Program Announcements or Requests for Applications, will be developed to facilitate needed research. A major thrust will involve civic and public interest groups in a collaborative effort to incorporate oral health messages and activities into general health programs.

Question. How is the adult and elderly public being made better aware of dental and oral health problems in their generations?

Answer. The NIDR produces and distributes educational leaflets for adults. Topics include fluorides, xerostomia (dry mouth), periodontal (gum) diseases, dental tips for diabetics and mechanical plaque removal. Also, the NIDR collaborated with the National Institute on Aging to develop an "Age Page" on oral health for older adults. Several posters have been developed to increase awareness among adults that they, too, benefit from community water fluoridation. The NIDR also collaborated with industry to produce two films for adults, "Fluoride the Magnificent Mineral," and "Prescription for Periodontal Health." Free-loan exhibits have been developed for use with adults to increase awareness on how to prevent dental caries and periodontal diseases. The American Dental Association and The American Dental Hygienists' Association have programs to heighten awareness among their members and the general public concerning the need for a lifetime of oral health.

The NIDR is supportive of initiatives in the private sector. The American Dental Association has initiated a Senior Smile Week to encourage older adults to improve self-care and use of professional services, and the American Cancer Society has developed educational programs on oral cancer--a condition more prevalent in older Americans.

Question. How much is being expended on this program and is it enough to meet stated goals?

Answer. In FY 1989, $500,000 is being expended on this program.

Question. What do you think the impact will be of new anti-tartar/anti-plaque mouthwashes and toothpastes on adult and elderly oral health?

Answer. Many of the new anti-tartar and anti-plaque products show promise in chemical tests of partially controlling tartar build-up and plaque accumulation, respectively. While this is a hopeful sign, it is not possible to assess what the magnitude of their impact might be, because a number of research questions have yet to be answered. In the case of tartar-control products, the effect appears to be mainly, if not entirely, on reducing tartar above, rather than below, the gum line. While tartar under the gums is likely to have an adverse effect on gum tissues, it is not clear what effect tartar above the gums has. Other research questions concern the influence of tartar under the gums on re-attachment of gingival tissue to the root of the tooth, and whether or not the presence of tartar encourages the accumulation of plaque. It also should be noted that most of the studies have been done on individuals who have had all existing tartar professionally removed prior to their using the product. Accordingly, definitive information is lacking on the effectiveness of these agents in reducing the amount of tartar already present in the mouth if used without benefit of professional care.

Dentifrices and mouthwashes aimed at plaque control have been more fully researched and a number of these products are effective not only in reducing the amount of plaque, but also in reducing gingivitis.

While these types of products represent a step in the right direction, continued research on new or improved formulations is needed to reach the full potential of this preventive approach.

## THEMATIC CENTERS FOR THE ELDERLY

Question. In the Justification (p. 219) you stated that the Institute, in collaboration with the Veteran's Administration and National Institute of Aging, issued in 1987 requests for applications for research centers on oral health in aging. Applications were due in March, 1988. Have the applications been received?

Answer. A total of 14 applications were received in response to the Request for Applications (RFA) by the due date of March 15, 1988.

Question. What is your evaluation of them?

Answer. The applications were submitted by institutions representing a broad geographic distribution. A preliminary review suggests that the science proposed appears, on the whole, to be quite good and in each case takes advantage of the unique Veterans Administration interactions available to the institutions. Some of the applications appear stronger than others when judged by criteria developed for the final evaluation of these center proposals.

Question. How long will it take to review and implement the applications?

Answer. The first phase of the review process consists of a triage mechanism, the second phase consists of reverse site visits, and the final stage will be completed in July when a meeting of the National Advisory Dental Research Council is to be held.

Question. When do you think these new research centers will be created?

Answer. We expect to establish these centers before the end of FY 1988.

Question. Is funding adequate for this program?

Answer. We believe that the 1989 President's budget represents an adequate level of funding. The NIDR plans on funding at least three centers this year.

## MERCURY STUDIES AND ALTERNATIVE BONDING MATERIAL RESEARCH

Question. NIDR scientists are investigating the quantity, rate, and mechanisms of mercury release from aging fillings. Mercury, like lead, can be toxic to humans if ingested in sufficient quantities. Alternative filling and bonding materials could eliminate the mercury problem. How serious is the problem of mercury leaching from dental fillings?

Answer. A review in 1987 on the potential hazards of the use of mercury in dentistry concluded that "while there is consistent evidence indicating release of mercury vapor from restorations during chewing, tooth brushing, and other oral activities, proof of a causal link of this specific source of the heavy metal to any major human health problem is lacking."

Apart from vapor released from amalgam restorations, the most common sources of mercury are foodstuffs, contaminated air, occupational exposure, and certain drugs and ointments. It is difficult to differentiate the effect of any one of these sources from all of the others under normal circumstances. Examination of blood and urine levels of mercury of individuals with and without amalgam fillings has shown the contribution from amalgam fillings to be negligible.

The current position of the NIDR is that "there is no documented evidence for recommending the discontinuation of the use of dental amalgams as a restorative material in dentistry. The removal of dental amalgam can only be recommended for those patients who have a true hypersensitivity to mercury or other constituents."

Question. What are the most promising alternative restorative materials for teeth in the immediate future?

Answer. The NIDR is currently supporting research to develop new, and improve existing, non-mercury-containing dental filling materials. Chief among these are composites or tooth-colored polymers reinforced by ceramic particles. However, limited clinical durability due to color change, inadequate adhesion to dentin, and loss of substance through wear has kept composite materials from reaching their expected potential. Researchers are continuing to seek solutions to these durability problems.

## COST OF DENTAL CARE

Question. A recent New England Journal of Medicine article by James Shaw states that in 1984, dental care in the United States cost $25.1 billion, about half of which was spent to restore or replace teeth damaged by dental caries. The article further stated that this figure represents 6.5 percent of all health expenditures and projected a dental care cost figure of $42 billion in 1990. Do you agree with that assessment in view of what you have reported about the generally improving dental health of the nation?

Answer. Dr. Shaw uses procedures for current assessments and future projections of health care expenditures developed by the Health Care Financing Administration (HCFA). In the case of dental care expenditures, NIDR believes some of these factors may not accurately reflect costs and lead to an overestimate of current and future expenditures.

Question. Do you agree with the article's 1990 projection of $42 billion for national dental care?

Answer. Future dental expenditures are very difficult to predict because so many variables affect dental expenditures. Because of the many factors involved, incorrectly predicting any of these factors could, and probably will, cause that projection to be inaccurate. For example, the HCFA projection includes a factor for general inflation as well as an estimate of inflation specific to dentistry. Both of these will be affected by general economic factors and public policy decisions which can change rapidly. The amount of new disease and the amount of treatment required because of previous disease were two factors that were not explicitly considered in the HCFA projections. However, trends in these factors will be very important to future growth in dental expenditures and are unlikely to change as erratically as general economic conditions. Because of the general decrease in the extent of dental caries that is occurring among children and young adults in the U.S., as well as the generally good health of older adults, we believe the growth in the amount of dental services provided will be moderate. If other factors, such as inflation, also are kept under control, dental expenditures are unlikely to grow to $42 billion by 1990.

Question. Won't advances in dental care technologies tend to decrease rather than increase the nation's dental cost burden?

Answer. Technical change can either increase or decrease health care expenditures. For many areas of health care, it is generally believed that technical advances have actually led to increases in expenditures. This is because treatment becomes available with new technology that was not available before. Most technical change in dentistry has not been of this kind. Instead, technical change has largely led to improvements in the prevention of dental disease. It also has provided new methods or materials which have increased dental productivity. These types of technical changes tend to decrease expenditures.

## PERIODONTAL DISEASES AND ORAL VACCINES

Question. A number of studies have shown that certain bacteria (streptococci and lactobacilli) cause tooth decay. Efforts have been under way in the United States and abroad for quite some time to develop vaccines to prevent tooth decay and periodontal diseases. Is the development of oral vaccines a practical approach to problems of tooth decay and gum diseases?

Answer. In cases of gum diseases, a vaccine is conceivable, but may or may not turn out to be practical. The successful vaccines developed in the past for many common diseases were based on evidence that the disease was caused by specific organisms and that the causative organisms were susceptible to host immune defenses. At present, we do not have sufficient evidence on causative organisms to determine whether vaccines for periodontal diseases will be feasible. However, there is accumulating evidence that some types of human periodontal disease may be caused primarily by specific organisms. For example, many studies have shown that the organism Bacteroides gingivalis is strongly associated with adult periodontitis and possesses numerous destructive characteristics. Thus, many investigators believe that this bacterium may be a major causative organism. Moreover, in preliminary experiments, vaccination of monkeys with preparations of B. gingivalis has provided protection against periodontal disease. These results suggest that a vaccine may eventually be practical, but at the moment the promise of this approach remains uncertain.

Caries vaccine research has led to an in-depth understanding of the virulence of the principal strain of bacteria that cause this disease, Streptococcus mutans, and has resulted in substantial advances in the areas of genetic engineering and immunology. Immunologists in caries research have found evidence for a common mucosal immune system in humans following ingestion of enteric-coated capsules containing potential caries vaccines. Phase I human vaccine trials with Streptococcus mutans immunogens have resulted in the production of salivary antibodies against this bacterium without untoward effects. Such vaccines have proven effective in animals to prevent disease; their efficacy in humans has yet to be determined.

Question. In other words, is research on vaccines worth the cost?

Answer. Vaccines against periodontal diseases would definitely be worth the cost. There are numerous examples in the history of public health that clearly show that the original expense of developing a successful vaccine is negligible compared to the savings in future health care costs made possible by the vaccine. Nor should it be overlooked that much basic knowledge can be obtained in the course of vaccine research, e.g., the identification and genetic characterization of causative organisms; the nature of host responses, and the role of co-factors in initiating or exacerbating disease (e.g., diet, other disease, use of tobacco or alcohol).

A safe and effective caries vaccine could be of considerable value in decreasing pain, expense and tooth loss associated with dental caries, especially in individuals at high risk for disease.

Question. Wouldn't it be more practical to improve dental care practices and information dissemination?

Answer. In the case of periodontal diseases, it is more practical to improve dental practices and health education because no effective vaccine is available. A successful vaccine might be more practical in the long run because it would require minimal time, effort and expense and ideally would provide a high degree of protection. In contrast, improved dental care practices and information dissemination demand much time, effort, and expense on the part of the patient and various types of professionals, as well as continued compliance to self-care and professional care regimens over the lifetime.

Methods that aid in preventing dental caries are widely available in the United States in the form of community water fluoridation, use of fluoridated toothpastes, and professionally applied fluoride gels and dental sealants. These efforts, as well as continued activities to improve the quality and availability of dental care and disseminate information to the public and the profession, have been major factors in reducing the burden of disease. Nevertheless, ongoing research to develop a safe and effective caries vaccine should not be neglected. Its potential application as a cost-effective, preventive measure for dental caries, especially in high-risk populations, should not be ignored.

Question. When do you project the development of an oral vaccine that can be put into general use?

Answer. It is not possible to predict when an oral vaccine could be put into general use for either periodontal diseases or dental caries. The Institute is encouraging research on the causative agents of periodontal diseases and this might yield vaccines directed toward specific forms of periodontal disease in the years ahead. The Institute will continue to encourage research in this area because of what has been learned about pathology and immunology and because the protection of individuals at high risk of dental caries is important.

## AIDS TRANSMISSION AND DENTAL PRACTICES

Question. There has been persistent speculation and apprehension over the past two years that people infected with the

HIV virus or AIDS can transmit the virus or disease via saliva and blood during dental care practices. It is stated on p. 229 of the Justification that "saliva is an unlikely route of infection for AIDS." How unlikely is "unlikely?"

Answer. Current evidence--based on studies of household contacts of AIDS patients as well as laboratory research--indicates that it is highly unlikely that AIDS can be transmitted through saliva. Further, there is now evidence that saliva contains a factor that can inhibit the ability of the AIDS virus to infect cells. This has been demonstrated in vitro and further studies to confirm these findings and identify the factor are planned.

The AIDS virus has been found in "whole" saliva--the fluid present in the mouth--but the consensus is that the virus is a contaminant from oral lesions or blood; it is not secreted by the glands. Because dental procedures frequently involve contact with blood or debris associated with oral lesions and treatment, dentists are urged to wear gloves, masks and eye protection and observe appropriate infection control procedures.

Question. Is there any possibility whatsoever that the HIV virus or AIDS can be transmitted via dental care practices?

Answer. There has been one case in the literature of a dentist, not identified with any known risk group, having contracted AIDS in the course of dental practice. The dentist in question did not wear gloves or follow other infection control procedures. The low risk to dental care providers has been confirmed in other studies by professional dental associations. For example, there were no seropositives in 1,193 dental staff tested in a study conducted by the American Dental Association. Even in cases where health care workers have known needlestick injuries or mucous membrane exposure to HIV-infected blood, the risk is very low: Out of 770 health care workers who sustained such exposures, only three have become infected.

Question. How aware is the dental profession of your current findings and views on this issue?

Answer. Although there is no direct information on this question, it appears that some dental professionals are concerned about the possibility that the HIV virus can be transmitted via dental care practices. To counter fears and misperceptions about the risk of contracting AIDS, as well as other infections, the NIDR is working with the American Dental Association, the American Dental Hygienists' Association, the Centers for Disease Control, and other health agencies in the dissemination of educational materials and guidelines for infection control addressed to all health care workers and the general public as well. These efforts appear to be improving understanding and compliance as measured by recent surveys. For example, in a national survey of dentists (1987) more than 80 percent of the respondents believed that barrier techniques (e.g., wearing masks, gloves, eye-protection) are "very effective" or "effective" in controlling transmission of infectious diseases.

Question. What can be done to further heighten public and dental practitioner awareness of the issue and is it worth doing?

Answer. Yes, it is important that both dental care providers and the general public have correct knowledge and understanding that dental care can be provided safely for all concerned when appropriate infection control procedures are used. Activities that will likely increase awareness among the general public include, but are not limited to, the use of the mass media: TV, radio, newspapers, magazines, leaflets, and posters, as well as personal and community-based discussion techniques. Strategies to reach dental care providers include: the use of videotapes, scientific articles, professional colloquia and study groups, Board Certifying Examinations, and dissemination of messages transmitted through commercial dental supply vendors and public health agencies.

## INCIDENCE OF ORAL KAPOSI'S SARCOMA

Question. What is the incidence of oral Kaposi's sarcoma in AIDS patients?

Answer. Reports of the prevalence of oral Kaposi's sarcoma range between 15 and 40 percent of AIDS patients, depending on the risk group. The prevalence appears to be highest among homosexual AIDS patients. Kaposi's sarcoma is most commonly found in the skin, oral cavity, and digestive tract, so that while definitive statistics are not available, one can expect that oral Kaposi's sarcoma represents a significant part of the total problem.

## AIDS BUDGET

Question. How much is being expended on research into AIDS-related oral disorders?

Answer. In FY 1989, the Institute expects to support approximately $7,000,000 in research on AIDS-related Oral Disorders, of which $3,526,000 is NIDR's allocated share of available funds for AIDS research.

## FLUORIDATION AND ALLEGED ADVERSE HEALTH EFFECTS

Question. It is well established in the dental research community that fluoridation of public water supplies as well as various fluoride mouthwashes and applications have resulted in a substantial improvement (50-65 percent) in dental health over the past 40 years. Yet certain skeptics continue to maintain that fluorides in drinking water can lead to cancer, kidney disorders, bone disorders and other malaises. Is there any epidemiological evidence that fluoridation of water supplies has any adverse effect whatsoever on human health?

Answer. Beginning with the pioneering studies conducted on fluoride in the early 1940s, the potential adverse effects of fluoridation of water supplies on human health have been a major area for research. This research has been described, evaluated and codified many times; most notably by the World Health Organization in Fluorides and Human Health (1970) and in the Appropriate Use of Fluorides for Human Health (1986), as well as by the American Association for the Advancement of Science in Continuing Evaluation of the Use of Fluorides (1979). Highlights from the studies of fluoride and human health prior to 1945, as well as more recent evaluations of alleged adverse effects of water fluoridation on human health were summarized in reviews by qualified investigators in 1983. Critical analyses of the various forms of misrepresentation which underlie the allegations of anti-fluoridationists have been published in the July and August 1978 issues of Consumer Reports. In 1985 the American Oral Health Institute published an in-depth critique, Abuse of the Scientific Literature in an Anti-fluoridation Pamphlet.

Based on these assessments of the issue, there is no epidemiological evidence which shows that fluoridation of water supplies at prescribed levels has any adverse effects on human health. In the United States, the prescribed levels vary between .7 and 1.2 ppm, depending upon annual mean maximum daily temperature of the specific area.

Finally, it should be noted that community water fluoridation at prescribed levels is supported by dozens of national and international organizations.

## DENTAL IMPLANT TECHNOLOGY

Question. NIDR is sponsoring an NIH Consensus Development Conference on Dental Implants in June, 1988 to look at health risks of implants, long-term effectiveness, and other health related issues. There has been considerable public and media discussion about dental implants over the past few years. What is the status of dental implant technology and how widespread in practice is it?

Answer. Dental implant technology has reached a stage of acceptability to many clinicians, patients, and some scientists. Much anecdotal evidence has accumulated indicating that several types of implants can be successful, but there is only a limited amount of scientific evidence of long-term clinical success. The American Dental Association Council on Dental Materials, Instruments and Equipment, which assumes responsibility for evaluating implants, has so far granted provisional acceptance (based on three-year data) for only one implant system, the Branemark titanium cylinder. No implants have been given the Council's full acceptance, which requires five-year data. Although it would appear that the official status of implant technology is limited, many points can be made to strengthen the case for implantology.

There is currently much research activity on implants involving the efforts of many competent, objective scientists throughout the world. These include engineers, physicists, materials scientists, surface chemists, pathologists and bone biologists, as well as clinical scientists with training in surgery, orthopedics, periodontics and prosthodontics, and statistics. Accelerated efforts on the part of such individuals are expected to put dental implantology on a sound scientific footing in a relatively short period of time. Perhaps the most promising development in recent years has been the advent of the Swedish osseointegration system, whereby cylindrical titanium implants become rigidly attached to the bone and appear to offer stable support for full and partial dentures for long periods. This development has provided encouragement and great impetus for investigators to carry out long-term clinical trials.

The magnitude of implant usage in the U.S. is difficult to determine. The most reliable estimate indicates that in 1987, approximately 27,000 patients, mostly within the 40 to 70 year age range, were treated with implants with an average of three implant fixtures per patient. Since 1985, there has been a dramatic rise in the use of osseointegrated implants placed within the bone, whereas the use of other types of implants has increased slightly. It also was estimated that in 1987, the number of dentists installing implants approached 10,000, nearly 10 times the number estimated for 1983.

Question. Is it as effective and risk-free as we have been led to believe?

Answer. It is expected that the forthcoming NIH Consensus Conference on Dental Implants will deal with the issues of safety and efficacy in a comprehensive and definitive manner and will produce an authoritative statement. At present, it is the general impression that treatment with implants in healthy patients poses little risk beyond an occasional instance of local infection around the implant. However, the presence of specific medical conditions puts patients in high risk category for implant failure and other problems. Conditions in this category include uncontrolled diabetes mellitus, alcoholism, blood dyscrasias, osteoradionecrosis, heart conditions involving valvular defects or prostheses, and therapeutic regimes of high cortisone dosages and of high dosages of immunosuppressive drugs.

Question. What, if any, are the risks of dental implants and how long will they last?

Answer. The main risk for healthy patients is local infection around the implant, which may necessitate removal of the implant. In some such instances, a second implant can be placed successfully in the same location as the failed site, or it may be determined that the remaining implant fixtures are sufficient for the anchorage needed, and the failed site needs only to be allowed to heal.

High-risk patients, such as those with poorly controlled diabetes, malnutrition, heart conditions involving anatomical defects or prostheses, high levels of cortisone or immunosuppressive drug intake are at risk for local and remote site infections that may not only result in implant failure, but also may cause serious systemic infection.

The average survival time of different implants has not been determined. However, Swedish investigators claim up to 20-year successful survival for osseointegrated implants, and some American clinicians claim that subperiosteal implants (which are placed directly overlying the jaw bone under the bone-covering soft tissues) have survived as long as 30 years.

Question. What are the future prospects of improvements in dental implant technology?

Answer. In view of the intense research activity currently taking place, the prospects for improvement are highly encouraging. It is expected that the next few years will witness the development of implants made of stronger material, better design, and more appropriate surface characteristics and that they will be installed by biologically compatible, efficient clinical techniques, and will have an indefinite life expectancy.

## FORTY-YEAR ACCOMPLISHMENTS AND EXPECTATIONS

Question. Dr. Löe, the Committee is aware that NIDR is celebrating its 40th anniversary this year. What have been the most significant accomplishments in dental research realized over that time and what do you expect research to achieve in the next 40 years?

Answer. Major advances began with the discovery that fluoride could help prevent dental caries and that both caries and periodontal diseases are bacterial infections associated with dental plaque. These discoveries led to an emphasis on disease prevention and to the development of many vehicles for fluoride: water, toothpaste, mouthrinses, gels, etc., and to the use of dental sealants to protect the chewing surfaces of teeth from decay. Dental research also pioneered in the use of social and behavioral science techniques to elucidate risk factors for disease, overcome dental fear, and develop more effective and efficient ways to enhance understanding and compliance with oral health promotion and disease prevention behaviors.

Over the decades restorative dentistry moved from traditional filling materials to new plastic polymers that could be applied with less drilling and removal of healthy tooth substance. Dental implants were developed as permanent tooth replacements. Diagnostic methods expanded to include digital x-rays, nuclear magnetic resonance, genetic probes and monoclonal antibodies enabling earlier, more accurate detection of oral diseases. Research on saliva led to discoveries of many components that help maintain the teeth and repair the oral tissues--even remineralizing small caries lesions in enamel. Saliva is also the source of antibodies and other components that protect against infection. The latest findings are that a factor in saliva inhibits the AIDS virus from infecting cells. New antimicrobial mouthrinses and antibiotics of the tetracycline family were shown to be effective against plaque and early stages of periodontal diseases.

Pain researchers made basic discoveries concerning pain perception and control, leading to new drugs for acute and chronic pain. Behavioral approaches, not dependent on pharmacological approaches, also have been added to the armamentarium for pain control. Cell and molecular biology research on the craniofacial tissues led to the identification and classification of the many types of collagen that are the major constituents of skin, teeth, bone and connective tissue, to the isolation and sequencing of genes important in oral tissue development, and to animal models for genetic diseases of tooth and bone. Dental scientists isolated numerous molecules in the extracellular ground substance of tissues important in the growth and differentiation of cells, as well as in wound healing, tissue repair and regeneration. This work has led to an understanding of how cancer spreads in the body and to new classes of drugs that can block cancer metastases. Research on oral infections has led to experimental vaccines for oral herpes infections and to insights into the mechanisms of latency and reactivation of disease. AIDS research has identified numerous oral lesions associated with HIV infection as well as explored important changes in immune cells and effects on saliva.

Over the next 40 years we expect to see an increasing reduction of dental caries in children, significant reductions in toothlessness, the routine availability of genetic and molecular approaches in diagnosing oral diseases, and even better restorative materials and methods. Patients at high risk for disease will benefit from new biomedical as well as behavioral approaches to prevention, including replacement therapy (introducing harmless bacteria to replace oral pathogens) as well as ways to regenerate lost soft tissue and bone (as seen in advanced cases of periodontal disease.) The scope of dentistry will expand to include the diagnosis and treatment of oral cancers and other oral soft tissue disease, orofacial pain conditions, sensory-motor dysfunctions and oral complications of systemic diseases.

## ORAL HEALTH OF OLDER AMERICANS

Question. Last year, the Congress expressed concern about the oral health of older Americans. We urged the NIDR to set its target the elimination of toothlessness in the United States and ensure that future generations of older Americans never again experience the oral health problems of past generations. What specific initiatives have you begun to further these aims and what are your plans for FY 1989 and beyond?

Answer. In Fall 1987 NIDR issued a Request for Applications for Research Centers on Oral Health in Aging, a collaborative effort involving NIDR, the National Institute on Aging and the Veterans Administration. We received 14 applications and expect to fund up to four such centers in FY 1988. Other collaborative activities include preparation of an oral health component for the March 1988 Surgeon General's Workshop on Health Promotion and Aging, work with the American Association of Dental Schools to develop geriatric curriculum guidelines and the addition of an oral health component to the ongoing Baltimore Longitudinal Study of the National Institute on Aging. The NIDR Epidemiology and Oral Disease Prevention Program is continuing to analyze the data on adults and seniors collected in the recent NIDR national survey, and will use this information as well as that derived from other data bases to help identify individuals at risk for oral diseases and to develop recommendations concerning tooth loss and how to prevent it. Furthermore, the NIDR is proceeding in the development of a major research and demonstration activity aimed at eliminating toothlessness and improving the oral health of all Americans. An advisory working group and several other groups of research specialists have been convened to advise the Institute and address the specific areas of dental caries, periodontal diseases and access and utilization of dental services. These activities will form the basis for expanded research efforts in FY 1989 focusing on increasing the knowledge-base on oral health in relation to aging and moving laboratory findings more rapidly into clinical application. The transfer process will include social and behavioral science research to develop new approaches to educating the public and practitioners and will enlist the aid of other health agencies, the dental community, private industry, consumer groups and the general public.

## DENTIST SCIENTIST AND RESEARCH TRAINING PROGRAMS

Question. Dr. Löe, would you please give us a status report on the Dentist-Scientist program. Are you recruiting the numbers you need according to your original projection?

Answer. No. By the end of FY 1988, we expected to have over 135 candidates in the Dentist Scientist Award (DSA) program. Instead we will be funding only 105 candidates.

Question. When will the first candidates graduate?

Answer. Four candidates in the Physician Scientist Award program for Dentists are expected to graduate in 1989. In 1990 the first class in the DSA program are expected to graduate--about 25 candidates.

Question. Also, have you undertaken any initiatives to augment the dental research manpower pool using the National Research Service Award program?

Answer. An ad hoc panel has completed a review of the NIDR NRSA program and has made recommendations that have been approved by the National Advisory Dental Research Council and the NIDR Programs Advisory Committee. The recommendations call for a substantial increase in the overall NRSA budget to allow for additional slots and up to five years of support for dentists in training programs pursuing Ph.D. degrees. The remaining recommendations concern review cycles, increases in stipends and institutional allowances, and other changes which would make the programs more attractive to candidates and, in this way, augment the research manpower pool--especially to increase the numbers of research-oriented clinical faculty in dental schools.

Question. Dr. Löe, does your 1989 budget provide funding for the fifth year of the Dentist-Scientist program?

Answer. The NIDR FY 1989 budget will allow the Institute to support the Dentist Scientist program at the same level of funding as in FY 1988.

## AIDS RESEARCH

Question. We recognize that AIDS is a pressing public health problem that the Nation is facing. What have been the major contributions of NIDR-supported researchers to the battle against AIDS?

Answer. NIDR research investigators have documented frequent oral signs and symptoms in HIV-infected persons, often before HIV infection has been confirmed. These include oral Kaposi's sarcoma, candidiasis, herpes and papillomavirus infections, unusually severe periodontal diseases, and a whitish lesion, most often seen on the tongue, called hairy leukoplakia. In addition, there appear to be specific changes in salivary components which may precede oral signs. In addition, NIDR scientists have discovered that a factor in saliva actually can inhibit the ability of the AIDS virus to infect cells. Immunologic studies have focused on monocytes, white blood cells which are infected but not killed by the AIDS virus, leading to further weakening of immune defenses and helping spread the virus in the body. Studies of Kaposi's sarcoma have led to new understanding of the nature of these cells and the development of experimental drugs which could be applied topically to prevent the spread of Kaposi's sarcoma. Techniques for generating human monoclonal antibodies to HIV have been developed. Other therapies under study include the production of synthetic proteins able to block attachment of HIV to immune cells and modifications of an orally implanted controlled-release device for the delivery of antifungal drugs. NIDR scientists also have advanced magnetic resonance spectroscopy to allow structural analysis of small HIV proteins which will be important in developing treatments and vaccines. In collaboration with the National Insitute of Allergy and Infectious Diseases, NIDR staff scientists have incorporated the HIV genome into mice as a potential non-primate model of AIDS. Epidemiologic studies are documenting the variety or oral lesions associated with HIV infection in longitudinal studies conducted in collaboration with the Walter Reed Army Institute of Research and the Veterans Administration.

## RISK OF ORAL TRANSMISSION OF AIDS

Question. What are the problems in terms of oral tissues and what is the risk of infection through the oral route?

Answer. The oral cavity is often the site of AIDS-associated lesions which can occur early and throughout the course of the syndrome. These include candidiasis, severe periodontal diseases, herpesvirus and papillomavirus infections, soft tissue lesions called hairy leukoplakia, and Kaposi's sarcoma. Some of these conditions are very painful and unsightly, affecting appetite and food ingestion. Oral infections also may spread systemically giving rise to respiratory or digestive diseases which can lead to death.

Current evidence--based on studies of household contacts of AIDS patients as well as laboratory research--indicates that there is very little likelihood of transmission of AIDS orally. HIV has been found in "whole" saliva--the fluid present in the mouth--but the consensus is that the virus is a contaminant from oral lesions or blood; it is not secreted by the glands. Further, there is now evidence that saliva contains a factor that can inhibit the ability of the AIDS virus to infect cells. This has been demonstrated in vitro and further studies to confirm these findings and identify the factor are in progress.

## AIDS RESEARCH COORDINATION

Question. How are you coordinating your activities with other agencies?

Answer. The NIDR participates in regular meetings of the NIH AIDS Executive Committee and other interagency as well as international advisory groups. For example, NIDR is a Collaborative Center of the Oral Health Unit of the World Health Organization and in March hosted the first international meeting of Collaborating Centers on oral manifestations of AIDS. NIDR consults and is consulted by the dental professional organizations in research, education, and practice and conducts workshops on AIDS research in which all these organizations participate. These groups, as well as the Centers for Disease Control, are cooperating in numerous activities aimed at educating the public and health care providers concerning AIDS transmission and appropriate infection control procedures for dental offices. NIDR also has an internal AIDS Task Force which serves as a conduit for information and planning activities, including collaborative research. We are confident that these formal and informal contacts assure the rapid exchange of findings and the smooth coordination of research efforts.

### RESEARCH CENTERS ON ORAL HEALTH IN AGING

Question. We note that NIDR is collaborating with the National Institute on Aging and the Veterans Administration to establish research centers on oral health. What has been the response of the research community to this proposal? Will you make any awards this year?

Answer. The three agencies issued a Request for Applications for Research Centers on Oral Health in Aging in Fall, 1987. Fourteen applications were received by the March 15 deadline and are currently undergoing an expedited review. The Institute hopes to fund up to four such centers in FY 1988.

## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. The NHLBI requested $1,307,963,000 in the FY 1989 Preliminary Budget to NIH.

Question. What was the Department's original request to the OMB?

Answer. The Department's request to OMB was $875,244,000 for the NHLBI.

### FTE'S

Question. What was the original FTE request to the NIH Budget Office?

Answer. A total of 875 FTEs were requested in the NHLBI Preliminary Budget to NIH.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The President's Budget included 817 FTEs for the Institute, compared to 825 FTEs in FY 1988.

## BEHAVIORAL RESEARCH

Question. In the area of basic research, how does behavioral research fit into the overall program priorities.

Answer. Basic research into physiologic/biochemical mechanisms linking behavioral and environmental factors to cardiovascular disease has demonstrated the importance of studying the interaction of two or more variables as well as the effect of a single variable on the disease process. For example, the synergistic impact of laboratory stressors and salt creates a condition of sustained elevated blood pressure that cannot be observed in studying these two variables independently. Adding genetic predisposition adds yet another dimension of complexity. Understanding these interrelationships are necessary if we are to understand the multifactorial nature of the disease process itself.

A similar situation exists with coronary heart disease. Although dietary factors play an influential role in the development of atherosclerosis, their contribution becomes enhanced when environmental stressors are introduced and experimentally manipulated. The obverse also holds true; behavioral/environmental stressors contribute modestly to the development of atherosclerotic plaque when animals are placed on a normal cholesterol diet in a socially stressful environment. When a high fat, high cholesterol diet is introduced, the synergistic interaction of stress and diet become readily apparent.

Thus, the conceptual framework of biobehavioral research permits a more comprehensive understanding of the complex, multivariate relationships between accepted risk factors and behavioral/environmental variables.

## HEART DISEASE

Question. Dr. Lenfant, do women with coronary heart disease require coronary artery bypass surgery as often as men? Explain?

Answer. Women with coronary heart disease do not appear to require coronary artery bypass surgery as often as men because coronary artery obstruction requiring mechanical intervention is less frequent in women. In the NHLBI Coronary Artery Surgery Study of patients with clinical evidence of coronary heart disease, 45% of women compared with 79% of men had coronary artery obstruction which could benefit from operative treatment. Furthermore, coronary heart disease is less frequent in women generally. Data from the Framingham Heart Study indicate that men 35 to 44 years old are five times as likely to develop coronary heart disease as are women in this age group, almost three times as likely from 45 to 54 years old, and almost twice as likely from 55 to 64 years old. Also, men die from coronary heart disease more often than do women, more than four times as often until age 45, about three times as often until age 65, and more than twice as often until age 75.

## CHOLESTEROL-LOWERING ATHEROSCLEROSIS STUDY (CLAS)

Question. What is the significance of the recently reported Cholesterol-Lowering Atherosclerosis Study (CLAS)?

Answer. The effect of substantial modification of blood cholesterol levels was assessed in the Cholesterol-Lowering Atherosclerosis Study through treatment with a combination of diet and drugs in men aged 40-59 who had bypass surgery and whose arterial lesions were assessed by the procedure known as coronary angiography.

It was demonstrated that the cholesterol-lowering treatment resulted in greater stabilization and less progression of lesions together with evidence of regression in one in every six subjects. These results, taken in conjunction with other studies, suggest that cholesterol-lowering not only slows down the progression of atherosclerotic lesions but can also lead to their shrinking or regression.

Over 200,000 people receive bypass surgery each year in the U. S. and over two million patients have experienced the procedure since its inception. The recent findings suggest that the cholesterol levels should be reduced in most bypass patients.

Question. Would you please describe the National Cholesterol Education Program?

Answer. The National Cholesterol Education Program was inaugurated in November 1985 with the goal of reducing illness and death from coronary heart disease by reducing the number of Americans with high blood cholesterol. It is a national partnership effort based on the model of the National High Blood Pressure Education Program. It has a coordinating committee comprised of representatives from major medical, public health, and voluntary health organizations such as the American Medical Association, the American Academy of Family Physicians, the American Public Health Association, the Association of State and Territorial Health Officers, and the American Heart Association. The committee has liaison representation from other Federal agencies such the Food and Drug Administration, the Centers for Disease Control, and the Department of Agriculture. The program also works directly with State Health Departments, with employers and unions, and with industry interests such as pharmaceutical and food companies. The program develops therapy recommendations and provides updated reports for health professionals and conducts a large public education program. Recently, it provided detailed recommendations for practitioners on detecting, evaluating, and treating individuals at risk. It has urged the public, via mass media, to know their cholesterol levels and understand the implication of their specific levels.

Question. Is the public responding to this program?

Answer. The program has been well received. Each month the Institute receives thousands of public inquiries. Since the program began, cholesterol was the most common topic for which information was sought. There are more inquiries on cholesterol than all other topics combined. In addition, visits to the physician for cholesterol have increased since the program began, which indicates that the message to have one's cholesterol levels checked is being followed. From data on the number of prescriptions for lipid-lowering, it is clear that more and more people are being treated for high blood cholesterol.

## MOLECULAR BIOLOGY

Question. I understand that the National Heart, Lung, and Blood Institute has initiated a major program in molecular biology. Why was this program initiated, and what do you hope to accomplish?

Answer. Modern molecular biology has profoundly influenced the course of basic and applied biomedical research. A host of new experimental techniques and strategies enable investigators to analyze--more efficiently and with greater precision--gene organization, modification, regulation, and expression, as well as protein structure/function relationships. Outside of a few notable exceptions, however, heart, lung, and blood investigators have been slow to adopt the techniques of molecular biology, and molecular biologists have yet to focus their attention on these important experimental systems. In order to promote the new research opportunities afforded by these methodologies, the Institute issued a Request for Applications (RFA) in June 1987 to establish a network of Programs of Excellence in Molecular Biology. Each Program will combine contemporary molecular biology techniques with more conventional research methodologies in order to provide a multidisciplinary approach to study and elucidate fundamental biological principles of cardiovascular and pulmonary system development, organization, structure, function, and pathological disease processes.

The application of molecular biological techniques could have a impact on the prevention, diagnosis, and treatment of cardiovascular, lung, and blood diseases. It may be possible to identify genetic sequences to serve as markers for risk of developing a specific disease, which will enable investigators to develop sensitive and precise screening procedures to identify people who are susceptible or predisposed to a given disorder, such as high blood pressure or coronary artery disease. These new diagnostic procedures will in turn lead to improved targeting of preventive measures. Secondly, molecular biology may provide new drug therapies, by providing the tools to rationally design new biologically active compounds, and by providing the methods to produce these clinically active compounds on a large scale. For example, important therapeutic agents such as human insulin, human growth hormone, and tissue plasminogen activator were developed through this technology. Lastly, molecular biological strategies may be used to explore and develop novel therapies, such as gene transfer techniques, to correct genetic abnormalities.

## NATIONAL BLOOD RESOURCE EDUCATION PROGRAM

Question. Dr. Lenfant, I understand you have begun a new program called the National Blood Resources Education Program. What is this program designed to do?

Answer. The National Blood Resource Education Program (NBREP) was launched by the NHLBI in 1987. The program has two goals: to ensure an adequate supply of safe blood and blood components to meet the Nation's needs; and to ensure that blood and blood components are transfused only when therapeutically appropriate.

To accomplish these broad program goals, the NBREP is working with intermediaries including major medical associations, voluntary health organizations, and community programs to educate health professionals and the public. By addressing both the need for an adequate supply of safe blood products from healthy donors and the appropriate use of blood and blood components by health providers, the NBREP will enhance the quantity and quality of the Nation's blood supply.

Question. How much is included in the President's budget for this program?

Answer. During FY 1988, we set aside over a half million dollars to enable the program to prepare materials for and to stage its developmental meetings of more than 25 national organizations which represent the program's Coordinating Committee. In FY 1989, there are a number of educational initiatives planned and slightly less than $1 million dollars have been set aside for them. The National Blood Resources Education Program is not a line item in the budget.

Question. In your professional judgement, is this enough?

Answer. In my professional judgement, no, this is not enough. However, with the resources available to it the Institute will set priorities and support those activities we feel are most important. Some of the specific activities planned for this next year can be described.

A public subcommittee is convening to review the state-of-the-art in public education in blood resources and to develop a communications strategy document which will serve as an overall framework and plan for the NBREP activities in this area. This subcommittee will recommend specific public education activities for the NBREP to undertake.

A Blood Resource IQ Quiz is being produced to raise public awareness to the need for blood donation and the existence of the NBREP. This publication will be disseminated to the general public. An expert panel will be convened to analyze the recommendations of the NIH Consensus Development Conferences on platelets, fresh frozen plasma, and red blood cells, and to develop a professional education document. This publication will be disseminated to health care providers, especially physicians. A national survey of physicians is being planned to determine baseline levels of knowledge, attitudes, and practices related to blood transfusion. Future expert panels will be convened to develop position papers on such topics as autologous transfusions, risks/benefits of blood transfusion, and other topics. Patient education materials on those topics will also be developed.

We feel the NBREP is off to a good start with several exciting activities planned in both public education and professional education regarding blood donation and transfusion.

## AIDS TEST

Question. Dr. Lenfant, why is it so difficult to develop an AIDS test that is more accurate that the ones we currently use? (ELISA and Western Blot)

Answer. The current HIV antibody ELISA tests used to screen blood donations detect antibodies and are set to be very sensitive, minimizing the risk that an infectious unit of blood will slip through. These tests do that job very well, missing almost no individuals who have formed antibodies. The licensed Western Blot test, or one that is equally well quality-controlled, is very accurate in confirming that there are truly HIV antibodies present. Unfortunately, there are a number, perhaps ten to fifteen percent, of uninfected individuals who have Western Blot results that are indeterminate. A few indeterminate results are seen in people who are just beginning to form antibodies to HIV. Other tests for HIV antibodies, nearly ready for use, will provide an alternative to the Western Blot and probably reduce the frequency of indeterminate results. There is a period of time between infection and the development of antibodies where neither test can detect infection.

Question. Are there efforts underway at the NHLBI to develop more accurate tests?

Answer. Yes, the NHLBI is supporting studies of more specific antibody tests similar to those that might become a substitute for the Western Blot. One procedure uses multiple sets of beads with different sizes to which the special reagents are attached. This uses the greater specificity of newer tests while at the same time allowing for the testing for several antibodies or antigens (such as viruses, like hepatitis B) with one pass through automated machinery.

The NHLBI is also supporting research to develop a very sensitive assay for HIV nucleic acids. A gene amplification technique (polymerase chain reaction) is being used to identify these viral nucleic acids that would otherwise go undetected.

## BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. The NIA submitted a request of $263,092,000 to the NIH Budget Office.

Question. What was the Department's original request to the OMB?

Answer. In 1987 the Department submitted a request of $173,391,000 to the OMB for the FY 1989 budget.

## FTE's

Question. What was the original FTE request to the NIH Budget Office?

Answer. The NIA submitted a request of 365 FTE's to the NIH Budget Office for FY 1989.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. A total of 339 FTE's has been allocated to the NIA for FY 1989.

## HIGH BLOOD PRESSURE

Question. I understand that the NIA is currently cosponsoring with NHLBI a full-scale clinical trial called Systolic Hypertension In The Elderly program or the SHEP program to assess the effectiveness of antihypertensive treatment in reducing the incidence of stroke and other cardiovascular disease. The two institutes are also looking at the mechanisms responsible for age-related increases in blood pressure. What is the status of the SHEP Clinical Trial?

Answer. The Systolic Hypertension in the Elderly Program (SHEP) is a large, double blinded, placebo controlled trial designed to determine the effect of treating isolated systolic hypertension (ISH) in persons aged 60 and over. This condition only occurs in older persons, and increases risk of stroke. The value of treatment has been controversial. Recruitment of patients began in March 1985 and concluded successfully in September 1987 with approximately 4,700 patients in sixteen clinical centers.

The average age of patients at entry was 71.6 years. Fifty-seven percent are female and fourteen percent are black. The design of the study requires that results of treatment remain blinded for the five years of the trial. A Data Safety Monitoring Board reviews confidential results periodically. This board met in May 1988 and voted unanimously to continue the trial as designed.

Question. Could you describe some of the major findings related to hypertension in the elderly as well as other research initiatives in this area that are being funded by the NIA?

Answer. On the average, systolic blood pressure rises about 20 mm (Hg) between the ages of 20 and 60. An additional steeper rise of 20 mm (Hg) occurs between age 60 and 80. These are averages. Individuals vary widely. A steep rise leading to hypertension occurs in some, while others show little or no rise in blood pressure with age. Reasons for these age-related changes in blood pressure are being studied by at least six groups of investigators supported by NIA.

Studies by several groups of investigators have shown that older persons are more sensitive than younger persons to the effects of salt, and respond more strongly to diuretics. Older persons have blunted responses to impulses from the autonomic nervous system. As a result, they have a greater tendency to drop blood pressure too low when they stand, and many respond poorly to some antihypertensive medications.

Question. How much money was spent in FY 1988 on research related to hypertension in the elderly?

Answer. The NIA anticipates spending about $6,604,000 on hypertension in the elderly in FY 1988.

Question. How much is requested in the President's Budget in FY 1989?

Answer. The NIA anticipates spending approximately $6,729,000 in FY 1989.

## GERIATRICS TRAINING

Question. Dr. Williams, I understand that the National Institute on Aging's report entitled Personnel for Health Needs of the Elderly through the Year 2020" found that "shortages of faculty members and other leaders with adequate preparation in aging and geriatrics are a serious constraint on the development of further activities in research and professional education programs." Is that correct?

Answer. That is correct. This is also documented in a recent report by the Institute of Medicine: Academic Geriatrics for the Year 2000 (Journal of the American Geriatrics Society, 35:773-791, 1987).

The shortage of leaders with adequate preparation in aging and geriatrics is critical because it limits both the quantity and quality of health professionals to serve the needs of older Americans. As noted in the Institute of Medicine report, the establishment of programs to develop enough leaders is crucial to the development of the needed numbers of health professionals in aging and geriatrics.

Question. Am I also correct that the current number of prepared teaching faculty in various professional and scientific fields range from 5 to 25 percent of total estimated needs?

Answer. Yes. The severity of the shortage indicates that new approaches are needed for the development of well trained faculty in geriatrics and aging.

Question. Given these findings, do you think it makes sense to eliminate the specific appropriations provided by Congress for geriatrics training?

Answer. I think support is needed for the development of academic leaders in geriatrics. This would be especially cost-effective because these leaders will in turn develop training programs for primary care providers and other health professionals. As noted in the Institute of Medicine report, development of such academic leaders can best be accomplished in "centers of excellence" in geriatric research and training. These centers are needed to provide the full range of clinical, teaching and research expertise needed for academic leadership.

Question. Dr. Williams, I understand the National Institute on Aging is developing plans to establish up to 10 Centers of Excellence for research and training in geriatrics. How much is included in the President's request for these centers and how many centers will this fund? In your professional judgement, is this enough?

Answer. The NIA did not request FY 1989 funds for the centers since the plans to establish the centers were still being developed at the time the FY 1989 budget was submitted. The estimated cost per center is approximately $1 million per year.

## ALZHEIMER'S CENTERS

Question. Dr. Williams, in 1984 this committee provided funds for the first Alzheimer's Research Centers. Today, there are 12 centers, including the two that were funded last year. How much is included in the President's FY 1989 request for these centers?

Answer. The NIA is requesting $13.5 million to fund all Alzheimer's centers at the full recommended levels.

Question. How much are we spending in FY 1988?

Answer. The NIA expects the same level of funding for the centers in FY 1988 and FY 1989.

Question. In your professional judgement, is the FY 1989 request enough to fully fund the existing centers? Is there a need for more centers?

Answer. Yes. The NIA anticipates funding the ADRC's at the full recommended levels in FY 1989. In the best professional judgement, an additional four Alzheimer's Disease Research Centers would be useful to expand the clinical and research base on Alzheimer's disease by initiating research projects in areas not investigated in the other ADRC's. For example: studying the vulnerability of the aging central nervous system to environmental toxins and the role of specific environmental toxins in the development of Alzheimer's disease; studying the role of infections in AD, including the so-called slow viruses, in the production of dementia syndrome in older people; and studying the genetics of AD to permit further identification, isolation, and characterization of the affected gene(s). Funding any additional ADRC's would require offsets against other public health activities consistent with the Bipartisan Budget Agreement.

Until now, the appropriated funds have allowed the ADRC's to focus on basic and clinical research in etiology and pathogenesis, develop diagnostic procedures, and understanding the clinical course. Only recently have efforts been turned to treatment such as the THA trial.

To address the mandate more completely, the ADRC's could engage in a large scale cooperative effort to provide more sophisticated diagnostic procedures to wider segments of the U.S. population and to test in controlled scientific fashion many of the rapidly proliferating treatment and management strategies.

The ADRC's could function as tertiary diagnostic, treatment, and training resources. They will link with existing, or develop, clinical, diagnostic, treatment, and management resources in contiguous population centers to establish scientifically and medically sound primary care services. This will at least partially eliminate the burden of travel for patients and families and will also broaden our knowledge of the nature of the disease and problems faced by those outside of the current ADRC network. Although at present we may not be able to prevent, treat, or interrupt the course of the disease, we can develop the technologies to preserve function, reduce excess disability and ameliorate symptoms such as wandering, insomnia, pacing, agitation, feeding difficulties, and incontinence. It is important to note that in order to fully develop research on treatment and management, we must more clearly understand the clinical course in pure AD, mixed AD and MID, and AD impinged upon by other common diseases and conditions of older people. If the goal is to preserve function, we must be able to predict the sequence and timing of losses so we can institute supportive interventions prior to the delay. It is probably easier and cheaper to support or maintain thar to retrain or reestablish. Initial work must focus on the behavioral failures and problems most likely to lead to institutionalization such as bathing and toileting and sleeplessness or wandering at night.

Specialized training for health care providers such as nurses, social workers, paramedical professionals, physicians, and family members is critical. Two issues vital in such a training program would be to address the skills and attitudes necessary to prevent provider care burnout, and maintenance of the patient's dignity by caregivers.

Efforts should be made to develop technologies by either modifying existing devices or methods or developing new ones that will make it easier to care for AD patients and/or compensate for their functional disability, for instance, feeding devices, memory enhancing instruments, and so on.

Existing resources established by Federal funds such as the ADRC's, should be better utilized to develop and test new methods and/or determine the efficiency of old methods for the treatment, management and care programs. Namely, the ADRC's could increase their efforts in training health care providers, serve as initial resources for developing and testing modes of treatment and care for patients, and serve as referral sources.

## OSTEOPOROSIS, HIP FRACTURES AND FALLS

Question. One of the major health problems affecting older persons is hip fractures either caused by osteoporosis or falls. As I understand it, Type II osteoporosis is the major cause of these hip fractures, affecting both men and women with gradual bone loss beginning around age 35 to 40. Could you describe the NIA's current interest in this (osteoporosis) area?

Answer. The NIA has active and growing extramural and intramural research programs which support studies related to osteoporosis in older age populations and the effects of aging on the etiology and progression of bone loss. The NIA works closely with the National Institute of Arthritis and Musculoskeletal

Diseases (NIAMS) to coordinate the osteoporosis programs supported by the two Institutes. At the requests of Senator Grassley and Congressman Snow, the two Institutes have just cooperated in arranging and conducting a special Congressional hearing on Osteoporosis. As a part of National Osteoporosis Prevention Week, including emphasis on opportunities for international research on this problem, NIA and NIAMS together with the National Institute of Diabetes and Digestive and Kidney Diseases and the National Osteoporosis Foundation, also conducted a special NIH research conference on Osteoporosis in February 1987.

More specifically, the NIA currently supports a wide variety of basic, clinical and epidemiological investigations which are designed to further the understanding of basic bone metabolism and mechanisms which cause bone loss and related fractures and to provide technology for detecting and predicting osteoporosis in high risk populations. Other studies assess the prevalence of the disease and monitor the progression of osteoporosis in aging cohorts. Still other research investigations are seeking ways to prevent osteoporosis, or design and evaluate therapeutic strategies which retard the disease process and/or restore the quantity and quality of bone lost in affected individuals.

NIA researchers are making great strides in osteoporosis research. With new instrumentation in single and duel photon absorbtiometry, quantitative computerized tomography, and quantitative digital x-ray absorptiometry, it is now possible to measure bone density in the appendicular skeleton, spine, and hip, and thus to assess risk and to follow the effects of therapy. There have been advances in identifying and quantifying risk factors such as age, activity, life style factors (nutrition, alcohol consumption, smoking etc.), drug use, systemic disease, race, body build, and estrogen deficiency. Studies are underway which are designed to determine the nature of the mineral component of bone and how the chemical and structure of bone changes with time, and what changes occur in pathological conditions such as osteoporosis. Scientists now have a better understanding of how bone-cell activity is regulated physiologically and how it can be manipulated pharmacologically. These examples illustrate just a few of the promising research leads that potentially hold the keys to bringing this formidable disease under control.

Question. What has been found regarding risk factors and therapeutic interventions for type II osteoporosis?

Answer. Though not universally accepted, patterns of age-related bone loss argue that there are two distinct types of osteoporosis. Over their lifetime, women lose about 35 percent of their cortical bone which is the predominant type found in the shaft of long bones and 50 percent of their trabecular bone which is the type concentrated in the pelvis, vertebrae and other flat bones. Men lose about two-thirds these amounts. A biphasic pattern of bone loss has been identified for both cortical and trabecular bone: a transient accelerated estrogen dependent post menopausal phase that occurs in women, and a slow bone loss phase that occurs in both sexes. Differences in the rate and timing of cortical and trabecular bone losses determine the patterns of fractures associated with osteoporosis.

The accelerated post menopausal, Type I, phase is associated with a high rate of bone turnover and a greater loss of trabecular bone. The slow, age dependent, or Type II, phase results mainly from impaired bone formation and loss of both cortical and trabecular bone. Type I results in crush vertebrae and distal radius fractures, while the type II syndrome is associated with wedge vertebrae and hip fractures which increase dramatically in very old persons as increasing numbers of men and women have bone density values that fall below the fracture threshold. Some speculate that the Type II syndrome in women is actually osteopenia superimposed on the accelerated bone loss of post menopausal osteoporosis.

Much less is known about the risk factors for Type II osteoporosis than for Type I. To date, the two most important factors associated with the Type II syndrome are decreased osteoblast function and impaired production of the physiologically active Vitamin D metabolite, leading to decreased calcium absorption and secondary hyperparathyroidism. Inadequate exposure to ultraviolet light or sun exposure and decreased renal production of vitamin D metabolites may exacerbate vitamin D deficiencies in susceptible older people. There appears to be little hormonal effect on Type II osteoporosis, which may indicate that its etiology is more closely associated with environmental factors. Hypochlorhydria, decreased production of acid by the cells of the stomach, whose prevalence increases with age, may also decrease calcium absorption, especially in those with marginal intakes. Some drugs commonly used by older people including some types of anticoagulents, anticonvulsants, diuretics, aluminum based antacids and tetracycline can also interfere with calcium homeostasis. The effects of all risk factors for bone loss encountered over a lifetime are cumulative.

Since patients with Type II osteoporosis have low bone turnover and have lost most of the bone they will ever lose, there is little evidence that estrogen replacement or calcitonin, an anti-resorptive agent, has any beneficial effects. At present, treatment consists primarily of calcium supplementation to counteract impaired calcium absorption, and increased efforts to reduce the risk of falls which can result in fractures. Maintaining an active exercise program may also help to minimize bone loss of Type II as well as Type I.

Ouestion. How much money did you spend in FY 1988 on research related to osteoporosis? How much did you request in the President's Budget for FY 1989?

Answer. The NIA anticipates that it will spend $6,663,000 in FY 1988 on osteoporosis research. It is estimated that the NIA will spend $7,044,000 in FY 1989.

Question. What level of funding would you need to adequately assess risk factors and disseminate appropriate public information about the prevention of Type II osteoporosis?

Answer. Since little is known about Type II osteoporosis and its risk factors, a great deal of research must be stimulated in this area. More research is essential in the areas of pathophysiology and therapeutic interventions for this syndrome. A better understanding of the epidemiology and prevention of falls is clearly needed to prevent osteoporosis related fractures, especially hip fractures, in older people. To date there are no prospective, double-blind randomized trials which are of sufficient size and duration to conclusively document the risks or the efficacy of therapeutic regimens. A research program of this magnitude would require a financial commitment of $3 to 4 million per year over five years for basic and clinical research and $4 to 6 million per year over a period of five years to conduct the necessary epidemiological studies and clinical trials.

The cost for the development and national dissemination of 550,000 copies of an NIA series "Age Page" is $17,000. A companion booklet on Type II osteoporosis with a similar distribution would cost an additional $23,000 for a total of $40,000. One hundred thousand dollars to $200,000 would be required to provide information to the electronic media, including a vidio press release ($24,000) and preparation of 30 second public service announcements ($5,000 - $10,000 each), and to popular and health professional magazines. The NIA already collaborates with professional organizations, including the National Osteoporosis Foundation, in preparing and distributing osteoporosis educational materials to the public.

Question. When would the state of the knowledge in this area be adequate to begin to disseminate information to the public?

Answer. Although information on therapeutic interventions is limited, it is clear that preventive measures regarding adequate calcium intake and life style habits can be communicated to the public now. Public education should be targeted to young people in their teens, before peak bone mass is achieved as well as to adults through out the life span. As part of preventive health services, older people should be routinely evaluated and counseled by health care professionals on the known risk factors for both types of osteoporosis, including lifestyle modifications, medications, exercise, dietary calcium and calcium supplements if necessary. Those with bone loss diseases should be apprised on an individual basis and given information on the known or likely risks and benefits of therapy offered.

Question. I also understand that recent research indicates that older people actually have a greater tendency to fall due to weak leg muscles. Could you describe some of these findings as well as those activities the NIA has undertaken to investigate ways to prevent falls?

Answer. The NIA is supporting a broad array of research aimed at preventing falls and the injuries associated with them. This research reflects the multifaceted nature of the problem. Much of the work concerns identifying the most important biomedical causes of falls in older people and is focussed on leg weakness, medication use, postural control mechanisms and dizziness. In addition, behavioral and environmental factors appear to play an important role in falls and an intervention study is now ongoing to determine if lowering these types of risks can reduce the incidence of falls and injuries.

Although leg muscle weakness is an obvious potential risk factor for falls in older individuals, the subject has not previously been well studied. NIA-supported projects are directly addressing this critical point by characterizing the relation between leg muscle strength and falls in older people who could potentially participate in leg strengthening programs, and assessing whether simple clinical tests of leg strength can screen for people at risk for falling due to leg weakness. These studies seek answers to some important questions such as: What is the potential of exercise programs to prevent falls? Which leg muscles should exercise programs strengthen, and how much? Are relative strengths of opposing muscle groups important? How can older people be identified whose risk of falls might be reduced through strength training?

NIA's fall prevention program is now moving into a new stage whereby biomedical and/or environmental interventions will be tested in a coordinated set of clinical trials for efficacy in improving mobility, strength and balance and reducing injuries in physically frail older individuals. A September 1988 workshop on this topic is being organized.

In addition, as recommended by the Working Group on Injury Prevention at the Surgeon General's Workshop on Health Promotion and Aging held in March, 1988, the NIA is discussing cooperative strategies with the Centers for Disease Control and the Administration on Aging aimed at reducing the incidence of falls and falls-related injuries in older people.

Question. What was the original request to the NIH Budget Office?

Answer. The initial 1989 NEI request to the NIH Budget Office was $275,000,000.

Question. What was the Department's original request to OMB?

Answer. The NEI budget contained in the DHHS request to OMB was $204,877,000.

Question. What was the original FTE request to the NIH Budget Office?

Answer. The original 1989 request was 230 FTEs.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The FTE allocation in the 1989 President's Budget is 204 FTEs, compared to 205 FTEs in 1988.

Question. As you described in your testimony, last year's appropriations bill provided the NEI with $1.1 million to develop a National Eye Health Education Program. I am pleased to see that plans for the development of this program are underway. When do you expect to launch the National Eye Health Education Program?

Answer. The National Eye Health Education Program (NEHEP) is in the early planning stages. The first major activity will be a national conference, to be held early in 1989, bringing together representatives from government and the private sector, defining and developing priorities relating to education and information needs in glaucoma and diabetic retinopathy.

Question. How much money have you requested for this program in FY89?

Answer. In 1989 $1.1 million was requested for the National Eye Health Education Program.

Question. You mention in your testimony that part of this national education program includes a full-scale effort to increase public and health professional awareness of research results that can be applied to preventing blindness from diabetic retinopathy. Could you describe this program in more detail?

Answer. Since the NEHEP is still in the early planning stages, specific program components are still being defined. NEI staff have met with other NIH staff to learn about similar programs that have been developed by other institutes. Based on our discussions, we decided that the NEHEP will be implemented using the health communications planning process that has been successfully used by other NIH institutes who operate similar large-scale programs, such as the National Cholesterol Education Program of the National Heart, Lung, and Blood Institute and the Cancer Prevention Awareness Program of the National Cancer Institute. This process consists of several steps leading to the development of health communications and education programs and means for monitoring and evaluating their effectiveness. We have also written to organizations around the world to learn of other programs in eye health education. Several strategy sessions have been held with representatives of significant constituent groups including the American Academy of Ophthalmology, the American Optometric Association, and the Centers for Disease Control. On April 30th, NEI convened a conference planning committee of representatives from selected organizations to help plan the national conference on eye health education. This group made recommendations regarding the conference purpose, agenda, speakers and topics, participants, format, outcome and products.

A national survey of public knowledge, attitudes, and practices related to eye care and eye disease is also being planned for later this year.

Question. Could you describe for the committee some of the major research advances related to the treatment and prevention of glaucoma?

Answer. If glaucoma is detected early and treated promptly, the progression of the disease can often be stopped or slowed, and loss of vision or blindness can be prevented. Research on treatment is along two main lines. One line of investigation is drug development. A new drug called para-aminoclonidine, for example, has been shown in preliminary studies to lower intraocular pressure without the cardiovascular side effects associated with standard medications. The other line of investigation involves multicenter clinical trials of treatment strategies. The Glaucoma Laser Trial (GLT), is testing the efficacy of argon laser in the treatment of new cases of the disease. Some preliminary information from the GLT should be available in the near future. A second major clinical trial, The Advanced Glaucoma Intervention Study is assessing sequences of therapy involving argon laser and standard surgery in advanced glaucoma to determine what is the best combination of therapies in patients who are no longer responsive to medication. A third clinical trial, The Fluorouracil Filtering Surgery Study, will determine if a drug, fluorouracil, is effective as an adjunct for improving the outcome of standard glaucoma filtering surgery. Results from each of these studies will assist clinicians in the treatment of glaucoma.

Question. How much money was spent in FY88 on glaucoma-related research? How much money is requested in the President's Budget for FY 89 in this area? How would this level of funding impact upon the ongoing glaucoma research and plans for initiating new research?

Answer. We estimate that $17,426,000 will be spent for glaucoma-related research in FY 1988. The President's Budget for FY 1989 requests $18,396,000. This level of funding would allow for the support of about the same number of research projects in FY 1989 as were supported in FY 1988. Any new research initiatives would have to compete with ongoing projects for the available resources.

## BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. The National Cancer Institute FY 1989 original request to NIH was $1,677.0 million, excluding AIDS.

Question. What was the Department's original request to the OMB?

Answer. The amount of the Department's original request to OMB for the National Cancer Institute was $1,303.8 million.

## FULL-TIME EQUIVALENTS

Question. What was the original FTE request to the NIH Budget Office?

Answer. The original FY 1989 full-time equivalent (FTE) request to NIH was for 2,312 FTEs.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. In the FY 1989 President's Budget, 2,094 FTEs are included.

## BY-PASS BUDGET

Question. Dr. DeVita, the NCI By-Pass Budget recommends $2,080,000,000 for the Cancer Institute in FY 1989. This is compared to the President's request of $1,593,536,000, including AIDS. What won't the Cancer Institute do under the President's budget that it would be able to do under your By-Pass Budget?

Answer. The 1989 request of $2.080 billion that was incorporated in the By-Pass submission represented the professional judgment level required to exploit the research opportunities that are available today in the cancer field. This level was determined with the advice and endorsement of both the President's Cancer Panel and the National Cancer Advisory Board and covers all aspects of the program -- the causation, detection, treatment and prevention of cancer. Incorporated within the By-Pass level were the resources necessary to achieve the goal of a 50 percent reduction in the cancer mortality rate by the year 2000. The President's Budget level, including AIDS, of $1.593 billion reflects a 8.4 percent increase over the current year and will permit the Institute to support the highest priority research areas in the cancer field. Of course, the By-Pass budget would require offsets against other public health activities consistent with the Bipartisan Budget Agreement. Specifically, the major differences in the By-Pass Budget and the President's Budget are as follows:

- An accelerated support level especially in the areas of prevention and treatment research, including a funding rate of 50 percent for competing research project grants, and expansion of applied prevention activities funded through the Cancer Prevention and Control budget item.

- An expanded resource program including an increase in the number and scope of cancer centers; a major program ($48 million) in facilities rehabilitation that support cancer research; a moderate acceleration of the training programs within the National Research Service Awards (NRSAs).

- The procurement of additional biomedical research computing capability through the acquisition of a supercomputer dedicated in the extramural research community as well as an upgrading of the existing supercomputer at the Frederick Cancer Research Facility.

- The resources necessary to expand the programs necessary to double the number of patients entering into clinical trials in order to more rapidly validate clinical protocols that would be effective in cancer treatment, including the doubling of Community Clinical Oncology Program awards.

Question. Are there any particular areas of the NCI budget that have suffered more than others in order to maintain the NCI commitment to ensuring a stable source of funds for research project grants?

Answer. The Institute has and continues to support basic research as our number one priority. Research project grants are the foundation such basic research. However, I do not think a fixation on number of awards is the most productive way to fund research. A fewer number of grants funded more fully is preferable. The recent flexibility afforded by the Congress concerning the number of grants will greatly assist in assuring an appropriate program balance.

There are elements of the cancer program that we have not supported as fully as the opportunities would permit because of funding a prescribed number of research project grants. These areas have included the prevention activities supported the Prevention and Control budget element, facilities upgrading and renovation, contract supported programs, such as Epidemiology, preclinical screening, and intramurally supported activities.

## BREAST CANCER/ALCOHOL CONSUMPTION

Question. Dr. DeVita, it was recently reported that a new study of 7,000 women has found no link between alcohol consumption and breast cancer despite a national study released last year to the contrary. In that earlier study, it was reported that there was a link between the consumption of even a few drinks a week and increased incidence of breast cancer among women.

The first study was supported by the National Cancer Institute while the more recent study was conducted by the Centers for Disease Control.

Dr. DeVita, what is your view on the link between alcohol consumption and breast cancer?

Answer. There have been nearly 20 published studies on this question to date, and the data have not been entirely consistent. The majority of case-control studies and all five cohort studies conducted have shown a positive association between alcohol and breast cancer. In general, these positive studies have found that women consuming moderate amounts of alcohol have a slight increase in risk for breast cancer as compared to non-drinkers. A minority of studies, including the large case-control study carried out by the Center for Disease Control (CDC), have not detected an elevation in breast cancer risk in relation to moderate drinking. While the link between alcohol and breast cancer is biologically plausible, whether there is such a link has not been definitively resolved.

Question. Does NCI plan to continue to study the issue in order to clear up the confusion brought about by conflicting federally supported studies?

Answer. If the small increase in breast cancer risk in relation to moderate alcohol consumption is sustained after further study, it would become a very important risk given the large number of women in this country who do drink. NCI is conducting several new research projects to resolve this question. These efforts include three cohort and two case-control studies that will gather more precise information on women's drinking habits, as well as metabolic studies of the possible mechanisms by which alcohol might increase breast cancer risk.

Question. Are some types of alcoholic beverages more likely to contribute to increased incidence of breast cancer than others?

Answer. Evidence from positive studies suggest that increased breast cancer risk is not confined to particular types of alcoholic beverages. Rather, the increased risk seems to be related to the amount of alcohol per se that is consumed. The data bearing on this question are rather limited, however, and this is one of the major questions that the new studies will be examining.

## CO-FACTORS

Question. Dr. Fauci, I understand there is a great deal of interest in determining how certain co-factors may affect the transmission of the AIDS virus or the progression of the disease. What do we know about co-factors and what kind of research is the NIH conducting related to co-factors and AIDS?

Answer. The concept of co-factors in the transmission of HIV infection stems from epidemiologic studies that have shown an association between several sexually transmitted diseases and HIV infection in this country and in Africa. A particular association of genital ulcer disease with HIV infection in Africa has led to the development of the theory that damage to genital skin and mucous membranes may facilitate transmission of the virus.

The difference in the epidemiology of HIV infection and disease progression in Africa as compared with Europe and North America has led to formulation of questions concerning what the effect of the multitude of endemic diseases is on the progression of HIV disease in individuals who are infected.

In vitro studies have helped to answer questions relating to the possible effect of co-factors on the progression of the disease, such as those that have shown enhanced expression of the HIV virus in T cells after being infected with DNA viruses or activated with mitogens. In the Multicenter AIDS Cohort Study (MACS), cytomegalovirus antibody titers were found to be strong predictors of the development of frank AIDS in HIV infected individuals, and consequently, a possible co-factor.

Several studies are currently being designed to study the effect of multiple infections and co-factors on the transmission and progression of HIV disease in both Africa and Latin America. The effect of possible co-factors will also be studied in several cohort studies of homosexual, heterosexual, and perinatal transmission supported by NIAID.

## STD

Question. How much will NIAID spend in FY 1988 on non-AIDS STD research?

Answer: In FY 1988, the NIAID estimates obligating $30,730,000 for research on sexually transmitted diseases other than AIDS.

Question. How much are you requesting in FY 1989?

Answer. For FY 1989, we are requesting $32,206,000 for research on sexually transmitted diseases other than AIDS.

Question. What research efforts are currently ongoing related to genital herpes and genital warts?

Answer. NIAID supports three levels of research on both of these sexually transmitted diseases. Basic research on the mechanisms of pathogenesis and latency is supported by regular research grants and also by program project grants. Basic research on the development of antiviral therapies for the virus that causes genital herpes is also supported by regular research grants and cooperative agreements. Efforts are also underway to develop a permissive cell system for papillomavirus, the virus responsible for genital warts. The availability of an *in vitro* replication system for papillomavirus infection will make research on the development of effective antiviral therapies against genital warts feasible. Several potential vaccines for genital herpes are in various stages of basic and preclinical development. A panel of experts convened by NIAID in October 1987 concluded that more basic information on the human immune response to papillomavirus was necessary before targeted vaccine development for genital warts was warranted.

The second level of research is preclinical testing of therapeutic and prophylactic agents. NIAID maintains under contract a guinea pig model of genital herpes infection. Two or three promising new antivirals are evaluated in this model each year. In March 1988, NIAID funded two groups of investigators to study several animal models of papillomavirus infection. These models will be used for preclinical evaluation of experimental therapies as well as for studies of the poorly understood natural history of infection.

The culmination of basic and preclinical research on viral infections occurs when an experimentally promising therapy is put to the test of the clinical trial. NIAID is currently supporting a trial of systemically administered interferon for the therapy of genital warts. A new award to evaluate combination therapies for genital warts will be made in September 1988. Several trials are ongoing to determine the optimum therapy for babies with neonatal herpes infections that can be acquired from an infected mother at birth. In addition, a natural history study will determine the frequency of virus shedding in asymptomatic women, the efficiency of transmission of virus from a woman who is asymptomatic but shedding virus to her baby, and the incidence of clinical disease in infected babies.

Question. How much are you requesting in each of these areas in FY 1989?

Answer. The NIAID is requesting $9,754,000 for genital herpes and $358,000 for genital warts in FY 1989.

## FTEs

Question. Dr. Fauci, how many FTE positions have been allocated to your Institute for FY 1988?

Answer. The FY 1988 column of the FY 1989 President's budget reflects 775 FTEs.

Question. How many for FY 1989?

Answer. The budget reflects 784 FTEs for FY 1989.

Question. In your professional judgement is the increase in FY 1989 enough to meet your responsibilities and the research needs of the NIAID?

Answer. The 1989 level represents an increase of 18 AIDS FTEs, and a decrease of 9 non-AIDS FTEs from 1988, for a net increase of 9 FTEs. In my professional judgment the rapidly expanding responsibilities of the Institute merit more substantial FTE increases, although offsets elsewhere have not been identified within HHS.

Question. Is the increase in FTE's for AIDS research enough?

Answer. The allocation for NIAID AIDS is 130 FTEs in 1988 and 148 in 1989. It is my professional judgment that the rapidly expanding responsibilities of the Institute merit more substantial FTE increases, particularly in association with the AIDS efforts, however, trade offs in other areas have not been identified.

## DRUG EVALUATION UNITS

Question. Dr. Fauci, I understand there is some concern in the scientific community over the funding of the AIDS drug evaluation units. Have you cut the funding for these units?

Answer. The budgets have not been cut nor was there any intention on the part of the NIAID to cut the allotted budget of any of the ATEU contracts. The perception of a cut stemmed from a complex situation involving significant increases in patient accrual to trials and unrealistic expectations of the FY 1988 increase in the budget. Over the past year the participating investigators were encouraged to enter as many patients as possible onto protocols. They responded appropriately; in the year in which protocols have been active, over 2,700 patients were entered on contracts which required only 1,100. At least in part, this was accomplished using funds unexpended from the first year of contract obligations. In some cases units are spending substantially more than their originally negotiated budget. Unfortunately, the magnitude of this situation was unclear. Hence, when the Institute attempted to allocate an additional $8,500,000 to these contracts, some investigators were told that they would receive a new annual award that was less than their ongoing level of expenditures. We are now meeting with the investigators of each unit to define the actual operating budgets. The goal is to honor the commitments that the Institute has made, and to begin a study of how much these trials should cost.

Question. How much will you spend on these units in FY 1989?

Answer. The Institute has included $55,660,000 in the FY 1989 President's budget for the support of the ATEUs.

Question. Have these units been more expensive than you initially anticipated?

Answer. As noted previously, the increased patient accrual created an expenditure rate in excess of our anticipated needs.

This problem uncovered a related issue concerning the cost of clinical trials in HIV infection. The observed cost per patient appears to be very high relative to other similar programs. Among the many factors involved in this expense, the following are most often cited by the program's investigators: 1) AIDS patients have an extremely complicated medical illness, in many ways more complicated than the average cancer patient, and the separation of costs for research from routine medical care is much more problematic; 2) AIDS patients require much more intensive nursing care than the "typical" clinical trial subject; 3) a variety of unique social needs and problems require special support for research to be conducted in this patient population; 4) a relatively high proportion of individuals do not have health insurance and do not qualify for Medicaid or similar assistance; 5) the intensity and expense of required laboratory monitoring studies; 6) the expenses associated with the program's remote data entry system; and 7) the fact that third party payers are more rigorous in the exclusion of costs which, in other settings, might be regarded as routine medical care unrelated to research. If these facts are true, then research support for AIDS clinical trials must include a variety of expenses traditionally not considered in the design of a clinical trials program. It is apparent that a clinical trials program of AIDS therapies, based upon traditional assumptions, may be seriously underbudgeted. In order to translate this vital national program's goals into a rationally planned and structured effort, it is necessary to understand its special requirements. This understanding will be difficult to achieve, but will be approached through a systematic study of the elements of costs associated with the program and an analysis of potential sources of efficiency that can be achieved.

Question. In your professional judgment is the FY 1989 request enough?

Answer. As previously stated, an assessment of the special requirements presented by AIDS clinical trials can be obtained only as a result of such a study. We will have a better idea of our needs upon the completion of this study.

NON-AIDS VACCINES

Question. Dr. Fauci, what vaccine trials are ongoing at your Institute other than AIDS?

Answer. The NIAID has ten ongoing major vaccine trials that are non-AIDS. They are listed below:

1. Live varicella (chicken pox) vaccine in children
2. Efficacy of annual inactivated influenza virus vaccines in healthy middle aged adults
3. Testing of influenza virus vaccines in school age children
4. Efficacy trial of an inactivated herpes simplex virus type 2 glycoprotein subunit vaccine
5. Efficacy of Haemophilus influenzae type b vaccine in a high risk infant population
6. Testing of rotavirus vaccines in Navajo Indian children

7. Field comparison of live and inactivated influenza virus vaccines
8. Efficacy trial of acellular pertussis vaccines in Sweden
9. Efficacy of malaria vaccine
10. Efficacy of rotavirus vaccines in children aged 2 to 4 months.

Question. How much is included in the FY 1989 budget request for these trials?

Answer. The FY 1989 budget request includes $7,151,000 for non-AIDS vaccine trials.

Question. In your professional judgement, is that enough?

Answer. The current scientific opportunities that exist in vaccine development are extraordinary. These opportunities point to the possibility of developing vaccines to prevent many of the age-old maladies of humankind. Many of these infections have evaded control for centuries. Malaria, schistosomiasis, rotavirus, and respiratory syncytial virus are four infectious diseases for which candidate vaccines will soon be in the clinical trial phase. In addition, new generation vaccines to prevent Haemophilus influenzae type b (Hib), pneumococcal infections, chicken pox, and influenza are also in the research pipeline. Resources to perform the necessary clinical trials of these vaccines are needed if we are to take advantage of the scientific opportunities that exist in the vaccine development field. It is particularly important to emphasize the need to do additional clinical trials of the improved pertussis and Hib vaccines. Both of these infections are of great importance in children. For pertussis, a follow-up clinical trial of the acellular pertussis vaccines compared, if possible, to the current whole-cell vaccine, is a critical priority. There are many reasons for this, but the two most important are that although the Swedish trial showed that acellular vaccines were effective in preventing whooping cough, there is an acute need to better define the immunologic factors that correlate with immunity to Bordetella pertussis. In addition, there are a number of different acellular vaccine candidates. It is critically important to do these trials if progress is to be made in the introduction of an acellular pertussis vaccine soon.

## BUDGET

Question. What was the original request to the NIH budget office?

Answer. In the FY 1989 preliminary budget submission to NIH, the NIAID requested $981,160,000.

Question. What was the Department's original request to the OMB?

Answer. For FY 1989, the DHHS sent forward to OMB a budget request in the amount of $692,822,000 for the NIAID.

## FTEs

Question. What was the original FTE request to the NIH budget office?

Answer. In the FY 1989 preliminary budget submission to NIH, the NIAID requested 865 FTEs.

Question. How does that compare to the FTE allocation in the President's budget?

Answer. The FY 1989 President's budget for the NIAID provides 784 FTEs.

## HEALTH PROFESSIONS

Question. Dr. Löe, the President's budget essentially eliminates all health professions training in the area of General Dentistry Residency Programs. Given all of the new developments and accomplishments in dental research you list in the NIDR budget justification, and given your Institute's efforts in the identification and treatment of the AIDS virus, does it make any sense to you that the federal government should eliminate the funding for General Dentistry Residency Training?

Answer. It is our understanding that the health professions programs supported by the Health Resources and Services Administration are categorical programs, including the general Dentistry Residency Program. These programs are being proposed for consolidation. The consolidated program will allow States to identify their highest priorities for health training, including dentistry, and support them through this new $40 million program.

## AGING

Question. Dr. Löe, I understand that the National Survey of Oral Health in Employed Adults and Seniors revealed that many older Americans do not enjoy good oral health. In fact the study showed that 42 percent of the seniors were missing all their teeth, and the remainder experience cavities on the roots as well as the crowns of teeth. Older Americans also have more serious periodontal diseases signs and symptoms than younger adults. How has the NIDR responded to these findings? What kind of initiatives have been considered?

Answer. The NIDR is developing a comprehensive oral health program aimed at reducing toothlessness and improving the oral health of all Americans, with emphasis on individuals at high risk for oral diseases. This would include many older Americans who grew up without benefits of fluoride and other oral disease prevention measures. The program will emphasize research to improve the knowledge-base in such areas as the effects of normal aging on the oral tissues as well as research to facilitate the rapid transfer of laboratory findings into clinical practice. The NIDR is collaborating with other government and non-government organizations in developing this initiative.

Also, NIDR, in collaboration with the National Institute on Aging and the Veterans Administration, issued a Request for

Applications for Research Centers on Oral Health in Aging in Fall 1987. Fourteen applications were received by the March 15 deadlines and the Institute expects to fund up to four such centers in FY 1988.

Other activities to improve the oral health of older Americans include the dissemination of the findings in the NIDR surveys, the distribution of educational materials concerning oral health problems common in older people, provision of films and speakers for the public, and collaboration with other health agencies to add an oral health message in initiatives to promote general health and well-being.

Question. How much would such initiatives cost?

Answer. The estimated cost for the oral health program initiative in FY 1989 is $2 million as provided in our budget request. As the program develops, the cost would increase to about $5 million a year, which we will factor into future budget formulations.

## AIDS/SALIVA

Question. Dr. Löe, what kind of studies are ongoing at NIDR to determine whether the AIDS virus can be transmitted through saliva?

Answer. There have been a few reports indicating the presence of the AIDS virus in saliva. In general, the virus was isolated from samples of "whole saliva"--the fluid present in the mouth. The consensus at present is that the virus is not secreted by the glands, but comes from oral lesions, fluids or blood emanating from periodontal lesions. Moreover, new studies by NIDR staff scientists suggest that saliva contains a factor which actually inhibits the ability of the AIDS virus to infect cells. This finding, combined with epidemiologic data and intensive study of household contacts of AIDS patients, not only fails to support a role for saliva in transmission of AIDS, but points to a protective role of saliva in inhibiting AIDS infectivity.

Question. What does the current evidence indicate?

Answer. The evidence strongly suggests that there is very little likelihood that AIDS can be transmitted through saliva.

## BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. The original budget request to the NIH Budget Office for FY 1989 was $153,848,000.

Question. What was the Department's original request to the OMB?

Answer. The Department's original request to OMB for NIDR was $112,629,000 for FY 1989.

### FTE'S

Question. What was the original FTE request to the NIH Budget Office?

Answer. The original FTE request made by NIDR to the NIH Budget Office for FY 1989 was 349 FTE's.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The allocation of FTE's in the 1989 President's Budget for NIDR is 332.

## QUESTIONS SUBMITTED BY SENATOR JAMES A. McCLURE

### IDAHO NUCLEAR ENGINEERING LABORATORY

Question. In the Peer Review Committee's report, a recommendation is made to hold the Power Burst Facility (PBF) reactor at the Idaho Nuclear Engineering Laboratory (INEL) on "standby" for a period not to exceed five years. Since the report also disapproved of the INEL proposal to eventually do clinical trials using the PBF, there has to be some reason not to recommend decommissioning the PBF. What do you envision happening over the next five years?

Answer. Although the site visit team did not look favorably on the proposed use of Boron Neutron Capture Therapy (BNCT) for treatment of glioblastoma multiform, they felt that BNCT research had promise for other cancers. BNCT research is currently being conducted by both national and international investigators. Because of its ability to generate epithermal neutrons, the INEL facility could be useful for BNCT research. This research should focus on neoplastic lesions other than glioblastoma multiform, including metastatic disease such as malignant melanoma. Improvements in boron-containing compounds will strengthen the BNCT research effort.

Question. On page 4 of the Committee's report, they recommend establishing a national task force or consortium to coordinate BNCT research and development. Do you agree with this recommendation? What can be done to facilitate this? Do you see that the INEL should have a significant role in this?

Answer. A coordinated effort is a logical approach to the development of this research area. Collaboration of researchers can best be facilitated by the use of workshops and the establishment of other groups for the sharing of research information. INEL could be a member of this consortium.

Question. The remote location of the PBF was cited as one of the major reasons for the disapproval recommendation. What could INEL do to overcome or compensate for the "perceived" remoteness problem?

Answer. The remoteness of the INEL facility led the site visit team to take the position of not recommending clinical trials there.

This would not, however, inhibit BNCT research at the preclinical level.

Question. Given that Idaho Falls has a new, modern secondary care hospital with resident neurosurgeons and medical oncologists, and a modern conventional radiation therapy facility, what was the basis for the conclusion that medical personnel required in a clinical trial are unlikely to be available?

Answer. The site visit team felt that there was lack of clinical trial expertise and experience in the team assembled for the proposed research. The site visit report deals with these potential problems in detail.

Question. In addition, the Mountain States Tumor Institute located in Boise is a well respected institution and has 15 years experience doing clinical trials. If MSTI had been taken into consideration for staffing purposes by the Committee, might is have alleviated medical personnel concerns?

Answer. Involvement of the Mountain States Tumor Institute would be advantageous to the proposal prepared by INEL. The principal investigator identified in the INEL proposal is at that Institute.

Question. Can you give me a general idea of the physical condition of patients suffering from glioblastoma? Is it a fact that only five percent of these patients live longer than a year?

Answer. The physical condition of patients suffering from glioblastoma multiform is dependent on many factors including patient age, tumor size and location, extent of surgical resection, and coexisting medical conditions. In general, patients with this diagnosis do not live longer than a year. Addition of chemotherapy and radiation therapy to the surgical treatment of this disease improves length of survival; however, most patients succumb to their disease within two years.

Question. Can you give me a brief outline on how clinical trials work? Are they always double-blind or blind trials? Is it conceivable that a protocol could call for comparing patients treated by BNCT to those treated by chemotherapy and surgery?

Answer. Clinical trials are the formal means by which effective treatments are identified. Patients with specific malignant conditions and acceptable general health are given full information about the study and are treated in a prescribed fashion. Randomized comparisons of treatments are the most definitive. Occasionally, such comparisons included double-blinded design but most studies do not.

Question. Did Review Committee mean it would disapprove of clinical trials at INEL both within the next five years and in the future as well?

Answer. The site visit team felt that clinical trials for the treatment of glioblastoma multiform were unlikely to succeed. This does not preclude other BNCT research efforts.

Question. The Committee's report discusses the advantage to the BNCT program that can be achieved by epithermal neutron, as distinct from thermal neutrons. The Power Burst Facility is a unique source for such neutrons at this time. The Committee notes that these high flux beams could be produced by low-energy proton accelerators.

Are there any such accelerators in the country?

Answer. Such accelerators do not exist in the country at this time.

Question. Have you any idea of the cost to build such an accelerator?

Answer. Cost figures have not been developed at this point in time.

Question. Do you envision PBF as a valuable research tool for a BNCT program?

Answer. The PBF might be a valuable research tool for BNCT research.

Question. Isn't it true that if we were to permanently close the PBF, we would lose the best epithermal neutron source available at this time?

Answer. Its potential for the production of a useful, epithermal neutron beam exists but has not been established.

Question. The cost for maintenance and surveillance of PBF in the standby mode for five years is approximately $12 million. This is approximately the same amount required to modify the facility as it is proposed. Would it made sense to modify the PBF now and have it available for a national BNCT research program (for example, beam optimization tests and animal studies)?

Answer. The site visit team felt that modification of the PBF at this time was premature. However, this proposal could be reconsidered as BNCT research advances.

Question. The reviewers recommend concentrating research on two critical points. The first of these is "developing a sufficiently intense beam of epithermal neutrons with a satisfactory spatial distribution for BNCT." Have the requirements for this beam been specified and can any existing facility besides PBF meet these requirements?

Answer. BNCT research projects are being developed at other reactor sites such as the Brookhaven National Laboratory and the Massachusetts Institute of Technology (MIT). The determination of beam characteristics should be a part of any biomedical research effort.

Question. What is the appropriateness and time frame for resubmittal of an INEL BNCT proposal for NCI peer review?

Answer. The appropriateness and time frame for resubmittal of an INEL BNCT proposal for NCI peer review are unknown at this time. This would be dependent upon INEL's ability to address areas of site visit team concern and advances in the research field.

Question. The review recognized the possible advantages of doing studies in large animal models to test the safety of the proposed treatment before the treatment was begun on humans. Additionally, the Committee noted that dogs with spontaneously occurring brain tumors may provide an excellent model to study the relative effects of therapy on tumor and surrounding normal tissues. Given that glioblastoma tumors cannot be induced in animals in a way that the tumor adequately duplicates the human tumor, but spontaneously occurring tumors does, and given that INEL has developed a program to find dogs with spontaneously occurring tumors with the assistance of veterinary neurosurgeons in Phoenix, Arizona and at Washington State University, wouldn't it be appropriate to proceed on this research in an orderly fashion instead of disrupting or discontinuing it?

Answer. Animal studies precede clinical trials in the accepted order of research projects. Results from this type of BNCT research would add to the scientific data base needed for the design of patient treatment protocols.

## QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

### RECOMBINANT TISSUE TYPE PLASMINOGEN ACTIVATOR

Question. Is rt-PA the new drug for heart attack victims, associated with an excessive incidence of hemorrhagic stroke (intracranial hemorrhage)?

Answer. The rate of intracranial hemorrhage with the currently recommended dose of rt-PA (100 mg) in myocardial infarction patients is on the order of 5 per 1000. A portion of this rate may be due to the almost invariable concomitant use of heparin and aspirin in these patients. When larger doses of rt-PA (150 mg) were used in early studies the rate observed was between 10 and 20 per 1000. These earlier studies used aspirin and heparin as well, which probably contributed to this rate. In the absence of anticoagulation and thrombolytic therapy the rate of stroke is 10-20 per 1000 but the mechanism is probably different.

### HYPERTENSION

Question. Modification of fat in the diet has been advocated in the management of heart disease patients and in those with high blood cholesterol. Does this advice pertain to patients with hypertension as well?

Answer. Presently there are conflicting data in the literature about modifying fats in the diets of hypertensive patients with respect to the effects of such modification on blood pressure. Some studies suggest that raising the polyunsaturated to saturated ratio of fats in the diet is associated with a fall in blood pressure, while other studies suggest that a change in the diet has no effect on blood pressure. Although recommendations for absolute reductions in fat are offered to hypertensive patients who are overweight, no specific recommendations with respect to the distribution of polyunsaturated and saturated fats in the diet are offered, unless the patient has high serum cholesterol or evidence of coronary heart disease. The patient is advised to lower dietary cholesterol intake and raise the dietary polyunsaturated to saturated fat ratio.

Question. Can some patients with hypertension eventually be taken off their antihypertensive medications?

Answer. Patients whose hypertension is controlled on drug therapy, especially those whose original disease was mild, can sometimes have their antihypertensive drugs reduced in a step-wise fashion. Although it is not always possible to totally eliminate all antihypertensive drug therapy, it is possible to at least reduce the number of medications and/or the dosage of medicines taken by the patient. Furthermore, there is evidence to suggest that this step-down therapy is more successful in patients who are also following nonpharmacologic therapeutic recommendations such as weight reduction if they are obese, and the avoidance of excessive sodium ingestion.

## SUBCOMMITTEE RECESS

Senator CHILES. The subcommittee will stand in recess until Thursday, April 28, at 9 a.m., when we will meet again in Dirksen 116.

At that time we will hear from the following institutes of the National Institutes of Health: Diabetes, Stroke, Child Health, Arthritis, General Medicine, and Environmental Health. Thank you.

[Whereupon, at 11:53 a.m., Wednesday, April 27, the subcommittee was recessed, to reconvene at 9 a.m., Thursday, April 28.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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THURSDAY, APRIL 28, 1988

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 9:10 a.m., in room SD–116, Dirksen Senate Office Building, Hon. Lawton Chiles (chairman) presiding.

Present: Senators Chiles and Burdick.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### NATIONAL INSTITUTES OF HEALTH

### STATEMENT OF DR. JAMES B. WYNGAARDEN, DIRECTOR, NATIONAL INSTITUTES OF HEALTH

ACCOMPANIED BY:

- DR. PHILLIP GORDEN, DIRECTOR, NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES
- DR. MURRAY GOLDSTEIN, DIRECTOR, NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE
- DR. DUANE F. ALEXANDER, DIRECTOR, NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT
- DR. LAWRENCE E. SHULMAN, DIRECTOR, NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES
- DR. RUTH L. KIRSCHSTEIN, DIRECTOR, NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES
- DR. DAVID P. RALL, DIRECTOR, NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

### INTRODUCTION OF ASSOCIATES

Senator CHILES. Good morning. This is our third and last currently scheduled National Institute of Health hearing on the fiscal year 1989 budget proposal. This morning we will focus on the six Institutes that cover the general subject matters of diabetes, neurology, general medicine, child health, environmental health, and arthritis.

Dr. Wyngaarden, if you would like to make any opening comments, please do so, and then please introduce the Institute Directors. We would like each Institute Director to make a brief statement regarding recent accomplishments and to highlight the 1989 request.

Dr. WYNGAARDEN. Thank you very much, Mr. Chairman.

I would like to introduce——

Senator CHILES. Did you have an opening statement, Senator Burdick?

Senator BURDICK. No.

Dr. WYNGAARDEN. If I may introduce my colleagues this morning; Dr. Phil Gorden, the Director of the National Institute of Diabetes and Digestive and Kidney Diseases; Dr. Duane Alexander, Director of the National Institute of Child Health and Human Development; Dr. David Rall, Director of the National Institute of Environmental Health Sciences; Dr. Murray Goldstein, Director of the National Institute of Neurological and Communicative Disorders and Stroke; Dr. Ruth Kirschstein, the Director of National Institute of General Medical Sciences; and Dr. Lawrence Shulman, who is Director of the relatively new National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Senator CHILES. Dr. Gorden, we will ask you to start.

## NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Dr. GORDEN. Thank you, Sir.

Mr. Chairman, the National Institute of Diabetes and Digestive and Kidney Diseases has a broad range of programs that addresses diabetes, the endocrine diseases, metabolic diseases, a whole host of digestive diseases and nutritional disorders. We also deal with kidney, urologic, and blood diseases. These clinical disciplines are bound together by a strong basic science program that, in addition, has made important contributions to several overall national priorities. These include biotechnology and research on the human genome.

In fiscal year 1989, each of our divisions will have projects in AIDS research.

Also emphasis will be placed on clinical and molecular genetic studies and diabetes, following up on considerable progress in this area in the last several years, as well as on endocrine diseases, cystic fibrosis, polycystic kidney disease, and a host of metabolic orphan disease. We will continue to strengthen our efforts in digestive diseases such as peptic ulcer and gallbladder disease.

Our nutrition program will specifically focus on major health risks such as obesity. In addition, we will have a major initiative in end-stage renal disease, including the kidney disease of diabetes mellitus, and will make a major effort to strengthen our urology program, which addresses problems of the prostate gland and urinary tract.

### PREPARED STATEMENT

Mr. Chairman, the fiscal year 1989 budget request for this Institute is $562,258,000, with an additional AIDS request of $3.65 million.

I would pleased to answer any questions you might have.

[The statement follows:]

# STATEMENT OF DR. PHILLIP GORDEN

I am pleased to share with you some of the advances this Institute has made toward the conquest of many of our Nation's most serious diseases -- diabetes, endocrine, and metabolic diseases; digestive diseases and nutritional disorders; and kidney, urologic, and blood diseases. We are also taking important steps toward realizing other national health priorities, such as combating AIDS and mapping the human genome. Equipped with the resources of modern biology, we are empowered as never before to develop improved diagnostic, therapeutic, and preventive methods to reduce the suffering that attends human disease.

A fruitful collaboration between our intramural scientists and other researchers from NIH and industry has resulted in the first production of a therapeutic human protein in animal milk. This work has expanded the frontiers of biotechnology by enabling us to produce in mouse milk a protein called tissue plasminogen activator, or tPA, which is used to treat heart attacks and blood clotting disorders. We expect that this technology will eventually enable the inexpensive and large-scale production of many therapeutic proteins in dairy animal milk, from which the proteins could be extracted. This advance thus provides a major benefit to patients, to the biotechnology industry, and to NIH.

Scientists are rapidly uncovering a vast array of genetic defects that underlie disease--highlighting the need for more knowledge about the human genome. NIDDK-supported studies have expanded knowledge about many genetic diseases, such as polycystic kidney disease, Tay-Sachs disease, Lesch-Nyhan disease, and Fabry's disease. By finding variations in DNA that occur near a defective gene, NIDDK researchers are providing markers that serve as "landmarks" for that gene, while also contributing to a chromosome map. We are actively participating in the international quest for the cystic fibrosis gene, for which several such markers have already been identified. Pinpointing the CF gene will enable us to study its function, design tests to permit population screening for carriers, and develop new therapies for those afflicted. From these and other disease-oriented studies, researchers are gaining an expanded knowledge about the human genome, which should better enable them to correct genetically-linked biochemical defects at the level of the protein or, some day, at the level of the gene.

Diabetes is an insidious disease that affects an estimated 11 million Americans and costs the Nation approximately $14 billion a year. Recent research has revealed that disordered regulation of the immune system can destroy the insulin-producing cells of the pancreas and cause insulin-dependent or Type I diabetes. Last year, I reported that a combination of genetic defects might underlie this disease. This year, NIDDK grantees have expanded knowledge about this multigene defect by pinpointing the area in an immune-regulating gene that may either promote susceptibility to or confer protection against the disease. We expect this discovery to lead to important prevention and treatment strategies for insulin-dependent diabetes, the type of diabetes that is most common in children.

In noninsulin-dependent or Type II diabetes, patients produce sufficient insulin, but their cells resist insulin's effect. New findings about the regulation of the insulin gene, the insulin receptor gene, and other control systems are helping us understand the nature of this resistance. This knowledge should enable us to identify those at risk, and possibly to prevent the development of Type II diabetes in susceptible people. Because this form of diabetes disproportionately affects minorities, we are making special efforts to understand and treat the disease in American Indians, Blacks, and Hispanics.

Institute-supported research has led to the discovery and testing of new drugs to treat or prevent the complications of diabetes, which include blindness, kidney disease, heart disease, nerve damage, and premature death. Two classes of drugs can now help prevent diabetic complications, especially in blood vessels and nerves. One type of drug prevents the abnormal linking of proteins that is driven by excess glucose in body fluids. The other corrects a chemical imbalance, thereby restoring nerve function and reversing nerve damage. NIDDK is also addressing the complications of diabetes through a major clinical trial in 1,400 patients with insulin-dependent diabetes. Now in its full-scale phase, the Diabetes Control and Complications Trial is attempting to compare the effects of two treatment regimens--designed to produce different levels of metabolic control--on the early vascular complications of diabetes.

Discoveries in endocrinology have opened new vistas into understanding cell communication and the regulation of cell function. An important fundamental discipline, endocrinology research underpins many NIDDK programs and has application to a wide range of diseases, including AIDS. For example, a recently discovered family of hormones, the inhibins, displays remarkable qualities: these hormones both inhibit and stimulate glandular systems. Inhibins may be important not only to fertility and reproduction, but may also have more diverse roles as growth factors that affect other vital processes, such as red blood cell production. Other endocrine studies in our intramural program are revealing the precise roles of calcium channels and regulatory proteins in controlling the secretion of parathyroid hormone, which in turn is a critical regulator of calcium levels in the body.

Inherited metabolic diseases represent a major research focus of the Institute. Many of these are orphan diseases, which often result in debilitating illness, mental deficiency, or premature death. In an exciting advance achieved through a Small Business Innovation Research grant, Institute-supported scientists have devised a way to synthesize and replace a missing enzyme in severely immunodeficient children. They have modified the enzyme to keep it intact in the blood, thus overcoming previous failures with enzyme replacement therapy. This research now offers promise for the modification of other enzymes to treat similar metabolic problems.

Diseases of the digestive tract are the leading cause of hospitalization and major surgery in the U.S. Twenty million Americans are treated annually for chronic digestive diseases, which cost tens of billions of dollars in medical care and lost productivity. Research is uncovering the causes of peptic ulcer formation, including factors that contribute to stomach acidity and bacterial infection. Consequently, several effective drugs are now available to treat and control peptic ulcers and other forms of ulcers.

Knowledge is fast accumulating about the interplay between the digestive system and other body systems, such as the endocrine and immune systems. The recent discovery of intestinal factors that can alter immune function has provided insights into the regulation of the immune response in the digestive tract. Understanding defects in gut immunity may be especially relevant to such diseases as inflammatory bowel disease and AIDS. In studies of inflammatory bowel disease, scientists have found a predominance of immune cells that augment immune responses in the gut, as well as defects in the regulation of immune responses in general. This research strongly suggests that the disease results from an excessive response to factors normally present in the digestive tract, and thus, these studies may pave the way to the development of approaches to downregulate such immune responses. Research into hormones affecting the gut is disclosing the complex, integrated circuits that mediate gut function, as well as relationships between behavior, such as food intake, and gut regulatory factors. New findings point to a defect in neural regulation that may underlie some motility disorders, such as constipation.

Recently, intramural researchers have successfully treated the three forms of chronic hepatitis with alpha interferon, a product of immune cells. Two clinical studies--one sponsored by a drug company and one sponsored by NIDDK-- will soon begin to explore this promising therapy for viral hepatitis, a major cause of debility and death.

Nutrition research transverses many areas of investigation at NIDDK and NIH. Studies are revealing the normal requirements of human nutrition and the role of nutrition in preventing disease. A critical focus of this research is the major public health problem posed by obesity. This year, NIDDK grantees identified a signaling molecule, called adipsin, that may regulate fat metabolism and energy balance, and could be a marker for some forms of obesity. Other major advances include the discovery of factors that may control fat cell mass and the development of new ways to measure energy consumption accurately. NIDDK is poised to launch new and intense research efforts on prevention of obesity. The

Institute plans to promote interdisciplinary research on the panoply of factors that may cause obesity, and the types of obesity associated with chronic diseases.

Approximately 85,000 patients with end-stage renal disease (ESRD) are on dialysis and more than 7,000 receive kidney transplants annually at an estimated cost to the Federal government that is approaching $3 billion a year. NIDDK research has been instrumental in the clinical introduction of synthetic human erythropoietin, a hormone that stimulates red blood cell production and thus corrects the anemia of ESRD patients. This hormone is now produced by genetic engineering as a result of the cloning of a gene by Institute grantees in collaboration with a private biotechnology firm. Erythropoietin has been shown to improve the quality of life of ESRD patients dramatically. Clinical studies supported by industry are now defining the application and uses of this important synthetic human hormone.

The Institute is sponsoring a major clinical trial to study the effect of protein and phosphorus restriction on the progression of chronic renal disease to irreversible kidney failure. The full-scale phase of this trial is expected to begin in 1988. The NIDDK is also in the process of establishing a Consolidated ESRD Data Base to meet research needs for better information on the ESRD patient population.

A major, multifaceted initiative is now under way to understand and ultimately control the development of kidney disease of diabetes mellitus, the most common cause of chronic renal failure in the U.S. As part of this initiative, we are exploring the epidemiology and natural history of this disease. We are also evaluating patients enrolled in the Diabetes Control and Complications Trial to determine if different levels of blood sugar control can affect kidney complications in insulin-dependent diabetes. In collaboration with a pharmaceutical company, we are funding a clinical trial of blood pressure-lowering drugs in these diabetic patients. This trial will evaluate encouraging findings that controlling blood pressure may slow the progression of diabetic renal disease.

In other studies, both intramural and extramural scientists are exploring how the body "switches" from producing fetal hemoglobin to producing adult hemoglobin. In the future, the ability to control this "switch" could provide a therapy for patients who produce defective hemoglobin, such as individuals with sickle cell disease and thalassemia. These patients would benefit greatly from the production of normal fetal hemoglobin throughout their lives.

Through NIDDK-sponsored research, several new drugs have been developed to treat a number of painful and costly stone-forming kidney diseases. In a long-term clinical trial, one drug consistently inhibited kidney stone formation in susceptible patients. In related research, an orphan drug has proven beneficial in treating some of the symptoms of the orphan disease cystinosis. Thus far, the drug has improved kidney function in affected children for up to six years.

Diseases of the lower urinary tract cause suffering for some eight million Americans each year and account for 20 per cent of deaths due to renal failure. Benign enlargement of the prostate gland has reached near-epidemic levels in men, with annual medical costs reaching over $1 billion. As a result of the discovery and characterization of a prostate-specific growth factor by NIDDK grantees, scientists can now explore how this growth factor may contribute to prostate enlargement and devise new research strategies for this disease. Interstitial cystitis, a chronic, poorly understood disorder of the bladder is another special emphasis area of the Institute. NIDDK will continue to scimulate research on the lower urinary tract, including studies targeted to prevent and treat AIDS.

To channel the biological revolution into the conquest of human disease, we are committed to recruiting talented people dedicated to careers in biomedical research. We have taken steps to strengthen research training and career development programs to foster this high priority commitment. Other special programs include our research centers in cystic fibrosis, diabetes and endocrinology, obesity, clinical nutrition, digestive diseases, and kidney and urologic diseases. The NIDDK is pleased to report that the six new Kidney and Urologic Diseases Research Centers, established in honor of the late Representative George O'Brien, are now fully operational. This year, we expect to create several new cystic fibrosis research centers to build on exciting progress in understanding this disease. Thus, at the close of the first NIH Centennial, we are on an historic threshold of science. We look back with pride on a century of research achievement and forward with confidence to yet another century of NIH research progress to improve the health of all Americans.

Mr. Chairman, the Fiscal Year 1989 budget request for this Institute is $562,258,000. I will be pleased to answer any questions you might have.

## BIOGRAPHY OF DR. PHILLIP GORDEN

December 22, 1934. Baldwyn, Mississippi. Married, two children.

Education: B.A., Vanderbilt University, Nashville, Tennessee, 1957; M.D., Vanderbilt University School of Medicine, Nashville, Tennessee, 1961.

Professional History: 1961-62, Intern, Yale University, New Haven, Connecticut. 1962-64, Assistant Resident, Yale University, New Haven, Connecticut. 1964-65, USPHS Clinical Fellow in Metabolism, Yale University, New Haven, Connecticut. 1965-66, USPHS Research Fellow in Metabolism, Yale University, New Haven, Connecticut. 1966-74, Senior Investigator, Clinical Endocrinology Branch, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health. 1974-78, Senior Investigator, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1974-76, Clinical Director, National Institute of Arthritis, Metabolism, and Digestive Diseases, National Institutes of Health. 1976-78, Visiting Professor, Institute of Histology and Embryology, University of Geneva School of Medicine, Geneva, Switzerland. 1978-present, Chief, Section on Clinical and Cellular Biology, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1980-1986, Clinical Director, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1983-1986, Chief, Diabetes Branch, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases, National Institutes of Health. 1986-present, Director, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health.

Professional Organizations: American College of Physicians, American Diabetes Association, American Federation of Clinical Research, American Society for Clinical Investigation, Endocrine Society, American Society for Cell Biology, Association of American Physicians, American Society for Biochemistry and Molecular Biology.

Honors, Awards: Alpha Omega Alpha Medical Fraternity, 1961. Doctor of Medicine (Honoris Causa) - University of Geneva, Geneva, Switzerland, 1986. Public Health Service Distinguished Service Medal, 1986.

## DIABETES INTERDISCIPLINARY RESEARCH CENTERS

Senator CHILES. Senator Burdick, do you have a particular field of interest?

Senator BURDICK. Oh, yes.

Senator CHILES. Which one?

Senator BURDICK. Diabetes.

Senator CHILES. All right, I will let you ask your questions.

Senator BURDICK. I just have a few short questions here.

Last year Congress requested NIDDK to begin implementation of the recommendations contained in the National Diabetes Advisory Board long-range plan to combat diabetes in 1987. The long-range plan recommended establishment of diabetes interdisciplinary research programs.

What efforts have been made by the Institute in this regard?

Dr. GORDEN. Sir, because of the complexity of diabetes, the multiple systems involved and the multiple different processes, we believe we need to involve more people from more different research disciplines, such as biochemistry, genetics, and so forth. We have held two colloquia already to discuss the kind of research that could be carried out if the resources were made available to bring all of these disciplines together.

So, we have actually begun the momentum to get this started in an intellectual sense, and we think that that would be the first step in terms of implementation. We think that this is really moving along in a reasonable way.

Senator BURDICK. You say bring the resources together.

What resources are you talking about?

Dr. GORDEN. Well, we think that first of all, we have to create the sort of intellectual movement to be sure of what it is that we want to do. We think that conceptually we have outlined an approach that in a way, makes sense so that if we had the resources to bring to bear on the problem, we would be prepared to move ahead very quickly.

Senator BURDICK. Could you give me a definition of resources? Are you talking about money?

Dr. GORDEN. Yes, sir.

Senator BURDICK. Have you got a figure?

Dr. GORDEN. Well, the recommendation from the Advisory Board is that eight of these programs be set up throughout the country at a cost of approximately $10 million.

Senator BURDICK. Do you have any information on this proposal that you could provide for the record?

Dr. GORDEN. Yes, sir; we have prepared a report, and we would be very pleased to provide that for the record.

Senator BURDICK. Fine.

[The information follows:]

# REPORT ON AN EVALUATION OF THE SCIENTIFIC FEASIBILITY OF THE PROPOSAL TO ESTABLISH DIABETES INTERDISCIPLINARY RESEARCH PROGRAMS

## Summary

In 1987 appropriations report language, both the Senate and House Committees on Appropriations urged the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) to consider the recommendations of the National Diabetes Advisory Board in its National Long-Range Plan to Combat Diabetes, 1987. One of the Board's recommendations advised the establishment of a new research mechanism, diabetes interdisciplinary research programs, within the Institute. The goal of these proposed programs would be to promote the integration of new research technologies in the basic sciences into diabetes-related research.

Excellent progress has been made in our knowledge of the causes, clinical course, and complications of diabetes. At the same time, remarkable technologic advances are emerging from the basic sciences and are expanding scientific discovery in many disease areas. The availability of these technologies is fostering an awareness that diabetes research could now benefit from a more interdisciplinary approach. Many experts in diabetes have expressed the importance of applying advanced technologies to the study of diabetes. The understanding gained from interdisciplinary research would enable researchers to build on current knowledge of diabetes, ultimately leading to better treatments and, potentially to ways to prevent and cure the disease. Furthermore, close collaboration would enhance the expertise of scientists who specialize in the study of diabetes, building the knowledge and sciences bases in the field.

NIDDK is now evaluating the benefits to be gained from an increased interdisciplinary approach to diabetes research. The Institute has organized a series of scientific colloquia to establish a dialogue between scientists representing several areas of basic science and those who have expertise in diabetes. This information exchange should provide the basis for planning for the fuller integration of basic science expertise into the study of diabetes.

The need for increased input into diabetes research from several technologically advanced areas of basic sciences is strongly supported by the diabetes research, training, and voluntary health communities.

## INTRODUCTION

During the past decade, scientists have made tremendous progress in developing knowledge about the causes, clinical course, and complications of diabetes. These advances have led to the development of new treatments for the disease and have now generated research opportunities that offer promise of preventing or curing diabetes in the future.

To provide a renewed focus for research efforts in diabetes, the National Diabetes Advisory Board published the National Long-Range Plan to Combat Diabetes, 1987. In formulating this document, the National Diabetes Advisory Board consulted with many experts in the field of diabetes, including representatives of a wide variety of organizations. The concepts developed in this report are largely based on the recommendation in the National Long-Range Plan to Combat Diabetes, 1987 to establish diabetes interdisciplinary research programs.

Congressional report language has addressed the Board's recommendation. In response to the National Long-Range Plan to Combat Diabetes, 1987, the Senate Committee on Appropriations wrote in its report that accompanied the FY 1988 appropriation bill for the Department of Health and Human Services:

> "The Committee is aware that the National Diabetes Advisory Board's National Long-Range Plan to Combat Diabetes, 1987 contains recommendations for two major new programs designed to enhance diabetes research and to improve translation of research results to clinical care. These recommended programs include: the establishment of eight diabetes interdisciplinary research programs to integrate the most modern scientific techniques into diabetes research; and establishment of a Diabetes Translation Center at the Centers for Disease Control to plan, conduct, and coordinate national efforts to transfer research advances into community level preventive health services. The Committee urges favorable consideration of these new initiatives as an expansion of the NIDDK research effort." (Senate Report No. 100-189, p. 99).

The House Committee on Appropriations stated in its report language relating to the FY 1988 appropriation bill for the Department of Health and Human Services:

> "Recently, the National Diabetes Advisory Board (NDAB) submitted an updated, long range plan on diabetes research and related activity. The Committee urges the Institute to carefully consider this plan. The NDAB recommended the establishment of diabetes interdisciplinary research programs which would accelerate the integration of basic science, such as immunology, genetics and molecular biology, with diabetes research and facilitate clinical application of basic research findings." (House Report No. 100-256, p. 65).

This report represents an effort to evaluate the scientific feasibility of the proposal to establish Diabetes Interdisciplinary Research Programs, in reponse to these recommendations.

## BACKGROUND

Diabetes is a complex metabolic disorder that can be roughly divided into two types: insulin-dependent diabetes (IDDM), which usually begins in childhood or early adulthood and whose victims require daily administration of insulin for survival; and noninsulin-dependent diabetes (NIDDM), which usually begins after age 40 and can often be controlled by diet and exercise, sometimes together with drug therapy.

Excellent progress has been made in our knowledge of the causes, clinical course, and complications of both types of diabetes. A better understanding of the disease has emerged from such research advances as the association of genetic factors with both types of diabetes, the discovery of animals models of IDDM, the identification of insulin receptors on cell surfaces, the finding of early markers in the prediabetic state of IDDM, and new knowledge about the role of diet and exercise in treating diabetes. New treatments are greatly improving the lives of diabetic patients. These include improved methods for measuring and regulating blood sugar, laser treatment for diabetic eye disease, strategies for pregnant diabetic women to have normal babies, treatments that reduce numbers of amputations, and drugs to treat high blood pressure.

To enable scientists to build on past accomplishments, experts are now recognizing the importance of applying the most advanced technologies to study diabetes. Revolutionary technological advances in the basic sciences are accelerating and broadening the scope of scientific discovery in many areas of biomedical research. A closer collaboration between basic scientists and diabetologists could promote the application of advanced basic science technology to the study of diabetes. The establishment of diabetes interdisciplinary research programs is a possible mechanism for promoting such collaboration.

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) has the lead responsibility for NIH diabetes research. Within NIDDK, the Division of Diabetes, Endocrinology, and Metabolic Diseases supports basic, clinical, and applied research by several mechanisms including investigator-initiated research grants, research contracts, and awards for the research training and career development of new investigators. The Division also has a centers program, consisting of two types of centers: Diabetes Research and Training Centers, and Diabetes-Endocrinology Research Centers. The Institute supports six of each type of center.

## MAGNITUDE OF THE DIABETES HEALTH PROBLEM

Diabetes is a major health public problem. Approximately 11 million Americans suffer from diabetes. Of these, six million have the disease, and approximately 5 million have diabetes but remain undiagnosed. Each year, more than 500,000 new cases of diabetes are identified. In terms of human suffering, people who have diabetes face a shortened lifespan and the probability of incurring debilitating complications, including blindness, heart disease, kidney disease, and loss of nerve function. Diabetes costs the Federal Government and the public about $14 billion annually.

The magnitude of the health care problems posed by diabetes provides a strong rationale for intensifying diabetes research. Experts in the field now recognize the need for increased interdisciplinary investigation to hasten progress in diabetes research.

## FOCUS OF CURRENT RESEARCH

As a result of advances in our understanding the causes of diabetes, the future holds tremendous opportunities for preventing and curing the disease. The following are examples of critical areas of diabetes research in which understanding has significantly progressed.

- Research is uncovering the genetic factors underlying the development of IDDM. Genes associated with the immune response have been linked to the development of the disease.

- Proteins produced by immune response genes have been shown to play an important role in IDDM. Researchers have also found antibodies to pancreatic islet cells in newly diagnosed IDDM patients. Immune mediators, called lymphokines, are now known to be associated with islet cell destruction.

- The autoimmune destruction of insulin-producing pancreatic beta cells continues for months or years before the disease is manifest. This knowledge may be important for the future ability to prevent IDDM. Techniques are now available to detect and track the progression of beta cell loss in IDDM patients.

- Two animal models have been developed in which diabetes progresses via mechanisms that closely resemble those in humans.

- Significant progress has been made in understanding the molecular events involved in insulin production, including the regulation of the insulin gene, the processing of insulin's precursor into mature insulin, and the mechanisms for insulin's release from the beta cell. Deviant forms of insulin have been isolated from some diabetic patients, pointing to defects in these systems.

- Studies of the insulin receptor are revealing how insulin acts on target cells. Scientists have gained considerable knowledge about the insulin receptor and about molecular events that occur during and after insulin binds to its receptor. These areas could all provide potential sites for defects in NIDDM.

## POSSIBLE SCIENTIFIC BENEFITS OF THE PROPOSED DIABETES INTERDISCIPLINARY RESEARCH PROGRAMS

Developments in several areas of basic research have expanded to create new research opportunities for increasing our understanding of diabetes. To hasten achievement in the quest to conquer diabetes, experts are now recognizing the importance of applying the latest basic science technologies to study the disease. Especially exciting and relevant are the revolutionary advances in fields such as molecular biology, genetics, molecular virology, protein chemistry, receptor signaling, immunology, growth control mechanisms, and genetic engineering. These areas of science offer new technologies that could broaden the base of diabetes research. Despite this explosion of new technologies, an insufficient number of investigators trained in these disciplines currently apply their expertise to diabetes research.

A heightened interdisciplinary approach could energize the field, enabling it to benefit from newly created and future technological advances. These technologies could create a rapid expansion of knowledge, spearheading the development of better treatments and, ultimately, possible prevention and cure of diabetes. For example, in the not too distant future, scientists expect to understand the causes of NIDDM at the molecular level. The study of animal models of IDDM could provide the basis for understanding causes and developing preventions for IDDM in humans. More knowledge about the immunology of diabetes could better enable the design of interventions, for example, the ability to intervene in the process of autoimmune destruction inherent to IDDM could form the basis of a powerful therapeutic strategy.

Specific examples of research areas that could benefit significantly from an interdisciplinary approach are:

- Gene mapping techniques to enable the search for diabetogenic genes.
- The expression and regulation of genes associated with diabetes, including the role of proteins that regulate gene expression.
- Immune system function, especially the activity of T cells, a subset of regulatory immune cells.
- Cell transformation techniques to develop diabetes-related cell lines.
- Improved techniques for islet cell transplantation in IDDM.

Many critical areas of diabetes research use methods that are rooted in basic science. Newer technologies can supplement these valuable research tools. With the rapid technological growth expected in the next few years, additional technologies will emerge that could be applied to diabetes research. Several promising high technology areas of investigation are now under way, including the evaluation of internal insulin infusion pumps that use glucose sensors, and assessment of islet cell and segmental pancreas transplantation. The challenge now is to build on the significant progress that has already been achieved.

Another benefit of enhanced interdisciplinary collaboration would be the expansion of the expertise of diabetologists into fundamental research disciplines. At the same time, basic scientists from many disciplines would get practical experience and exposure to the needs and opportunities in diabetes research to which they could apply their expertise. The cultivation of this bi-directional research expertise would be a long-lasting benefit to the field.

Thus, increased interdisciplinary investigation, via mechanisms such as diabetes interdisciplinary research programs, could broaden the science base; enhance investigator expertise; and, most importantly, hasten improved understanding of the underlying disease processes in diabetes.

## RELATIONSHIP OF PROPOSED DIABETES INTERDISCIPLINARY RESEARCH PROGRAMS TO NIDDK'S EXISTING DIABETES CENTERS

NIDDK's existing Diabetes Centers are each supported by a core center grant that provides funding for both shared resources and pilot/feasibility studies. However, establishing and maintaining support for each of the separate research studies conducted at such a center is the responsibility of each of the individual investigators who wish to conduct research at that center. As a result, a variety of investigator-initiated research project grants are associated with a core center grant at each of the existing centers. Such an arrangement provides a flexible and appropriate mechanism for long-term support of many diverse research projects that collectively span the entire spectrum of basic, clinical, and behavioral research disciplines. The variety of diverse research projects which exists at each of the existing Diabetes Centers fully reflects the fact that diabetes and its complications affect virtually every tissue and organ system in the body. And for these reasons, it would not be desirable to have any strong, centralized direction or a highly specialized scientific focus within the overall context of diabetes-related research within the existing centers. Rather, each of these center programs has evolved around the scientific interests of affiliated investigators who have been encouraged to pursue excellence in any promising area of diabetes-related research.

Although there are many strengths to the core center concept upon which NIDDK's existing Diabetes Centers are based, the core center grant would not be appropriate for the proposed Diabetes Interdisciplinary Research Programs which will require a more specialized focus. In this regard, the proposed programs will feature collaborative efforts between clinical diabetologists and basic scientists that are expected to bring new insights to our understanding of the causes of diabetes and its complications and to provide the basis for development of improved medical capabilities for diagnosis, treatment, cure, and ultimately prevention. With an interdisciplinary focus, this program will also require a greater degree of central direction than is appropriate at the existing centers. Therefore, the proposed interdisciplinary research programs would emphasize support for a network of specialized research projects within a matrix of research cores. Although each of these specialized research projects would have its own Principal Investigator, these projects would be developed as part of a coordinated research program under the leadership of a single Director. Thus, the proposed centers are likely to be Specialized Centers of Research (P50 SCOR grants) that would compliment the existing Diabetes-Endocrinology Research Centers (P30 core center grants) and Diabetes Research and Training Centers (P60 comprehensive core center grants).

## COLLOQUIA TO EVALUATE THE CONCEPT OF DIABETES INTERDISCIPLINARY RESEARCH PROGRAMS

NIDDK is presently evaluating the concepts underlying the establishment of diabetes interdisciplinary research programs to assess the potential benefits to diabetes research. To develop understanding in this area, the Institute has organized a series of scientific colloquia, which open a dialogue between experts in the diabetes field and researchers with basic science expertise. The colloquia provide a forum in which diabetes experts and basic scientists discuss the potential contribution of relevant fields of basic science to diabetes research.

The series is comprised of three colloquia. The first, Genetics and Diabetes, was held on February 12-13, 1988. Participants discussed the application of state-of-the-art genetic approaches (some of which have been used successfully to locate genes related to other diseases) to find genes that could play roles in causing diabetes. Future scheduled colloquia are: the Colloquium on Gene

Regulation and Cellular Signaling in Diabetes, April 8-9, 1988 and the Colloquium on Immunology and Diabetes, November 14-15, 1988.

Through these meetings, the Institute hopes to be able to evaluate thoroughly the benefits that could be gained from more intense collaboration between the diabetes and basic science communities. With this information, the Institute would then be better able to address the issues raised in the National Diabetes Advisory Board's National Long-Range Plan to Combat Diabetes, 1987.

## RECOMMENDATIONS OF PROFESSIONAL AND VOLUNTARY ORGANIZATIONS

The concept of broadening diabetes research to incorporate technologically advanced and scientifically relevant areas of basic research is strongly supported by the professional and health voluntary diabetes communities. Many expert scientists in diabetes research have pointed out the need for an increased interdisciplinary research approach. The American Diabetes Association and Juvenile Diabetes Foundation were very much involved in the formulation of the National Diabetes Advisory Board's National Long-Range Plan to Combat Diabetes, 1987 and strongly support the concept of expanded interdisciplinary research in diabetes. It is generally recognized in the diabetes community that highly talented investigators would be interested in applying to the Institute to establish interdisciplinary research programs, if additional resources were made available specifically for this purpose.

## CONCLUSION

Based on the foregoing analysis, the concept of establishing NIDDK diabetes interdisciplinary research programs is considered scientifically feasible and meritorious. It is strongly recommended that the concept be fully explored during the coming year.

## DIABETES CENTERS

Senator BURDICK. How will these programs that you referred to differ from the existing diabetes research centers?

Dr. GORDEN. The existing diabetes centers are of two types. They are core centers that bring together a particular type of research resource such as a particular type of laboratory doing a particular type of analysis, and there is a series of these built around a given research program. An extension of this concept focuses on training/translation activities. These are two different types of centers; one related to a basic research effort, the other related to training and translation.

The proposed new centers would be a different type of effort. This would be an effort to reach into basic science departments and bring clinical scientists and basic scientists together so that the problems related to diabetes can be communicated. In such a center more modern techniques—molecular biology and immunology and a number of other techniques that are being carried out by people who do not know very much about diabetes could be brought together to deal specifically with problems that relate to diabetes.

Senator BURDICK. With some kind of training?

Dr. GORDEN. It would involve training. It would involve an interchange of what the problems are and how we would take the next steps to resolve those problems by utilizing technologies that are very new and are not being utilized by people who are the main stream of the diabetes research movement today.

Senator BURDICK. Why did we not do these things yesterday?

Dr. GORDEN. Well, I think, in part, because much of this is really just emerging. What we are trying to do is capture an emerging field. I think that eventually all these things will happen, as you suggest, but we feel they will happen at a much more rapid pace if we can take advantage of those individuals and those techniques and those technologies now. We think this is the way to do it.

Senator BURDICK. Fine.

How many research centers do you envision it is possible to establish somewhere in the future or near future?

Dr. GORDEN. In the diabetes area we have existing 12 centers. The recommendation of the National Advisory Board is that we establish another eight interdisciplinary centers.

Senator BURDICK. Are you recommending that in this year's budget?

Dr. GORDEN. The National Diabetes Advisory Board is recommending that.

Senator BURDICK. Well, Mr. Chairman, you have got a recommendation.

Thank you.

Senator CHILES. I am sure I will hear from you.

Doctor, how does diabetes get into ulcers and stomach disorders?

Dr. GORDEN. Well, specifically, diabetes does not. We encompass a number of different medical problems within our Institute, and ulcer disease is one that is dealt within our Division of Digestive Disease and Nutrition. We have three extramural program divisions, one related to diabetes, endocrinology, and metabolism; another related to digestive diseases and nutrition; and another to kidney, urological, and hematologic diseases. They do not really interrelate directly, except at a more basic level of research.

Senator CHILES. So that is just part of the division that was set up?

Dr. GORDEN. That is just an administrative organization.

## DIABETES CLINICAL TRIAL

Senator CHILES. In your 10-year trial with the 1,400 diabetic individuals to test whether or not careful control of blood sugar level will slow the onset of diabetic complications, we are one-third of the way through the program.

What is the status of it now, and does it look like it needs to run out the 10 years?

Dr. GORDEN. The 10-year projection was from the beginning of the formulation or phase 1 through completion. We are now in the second year of phase 3, the full-scale project. Recruitment of patients is now complete for one leg of the study and is about 80 percent complete for the other. We now project that it is likely to run for the next 5 to 6 years through this third phase of the trial.

Senator CHILES. What kind of results do you think you are getting out of it?

Dr. GORDEN. At the present time we are getting the predicted results, that is, what we had hoped for. We have been able to separate two groups, an intensively insulin-treated group and a group that is treated by more conventional means. We have been able to separate the metabolic control levels of these two groups, and it has been consistent over the last 2 years. That was proven in the feasibility phase and in the 2 years of the full-scale trial. All of the initial goals that were set for the trial have essentially been met, and now it is really a question of just following through with the additional recruitment and the long-term followup of those individuals to determine the outcome.

## DIABETES DRUGS

Senator CHILES. I see you were talking in your full statement about a drug or several drugs that would help to prevent some of the problems that come from diabetes.

Senator BURDICK. The complications?

Senator CHILES. That is right.

Tell me something about that. Would that be in the normal diabetic patient?

Dr. GORDEN. All diabetic patients, whether they have the insulin-dependent variety, the so-called childhood type or the adult type, are subject to the same type of complications related to their eyes, their kidneys, their blood vessels, and so forth. We are attempting to address these problems at several levels. One major effort is the trial that you have mentioned. This trial is an attempt to improve overall metabolic control because we believe that it is the metabolic area that leads to these other complications.

Now, if we could, we would like to deal with those complications at a more local level, that is, at the level of the tissues that are actually being affected. One drug, known as sorbinil, is an agent that inhibits certain enzymes that have to do with the control of glucose or blood sugar at the local tissue level. That drug is being tested by us and also by other Institutes—the National Eye Institute has a large study. We are involved in this research mostly at the neurologic level, studying nerve function in diabetics.

There is another new drug that appears to have a beneficial effect, at least in animal trials and very early clinical trials. It sppears to help prevent a kind of cross-linking in proteins that seems to take place as part of the chronic complication phase of diabetes. There is a great deal of promise at least at the animal level, and these drugs do not appear in initial clinical trials to be toxic. We are very hopeful that this approach might offer not a complete cure, but something that will forestall these complications.

Senator CHILES. Well, normally they say a diabetic has a much shorter lifespan, and so what you are talking about is something that could expand that.

Dr. GORDEN. Yes.

Senator CHILES. And that would be something that, if there are no side effects, they could take that drug on some kind of a regular basis?

Dr. GORDEN. Exactly.

PROGRESS IN DIABETES RESEARCH

Senator CHILES. That sounds promising.

We see the bumper stickers at times that say "Insulin Is Not a Cure."

Where are we in regard to trying to find a cure?

Dr. GORDEN. In the last several years, we have focused on an important process in the so-called type I, or the juvenile onset type of diabetes, which most prominently affects children but also affects adults. We know that there is some type of immune disruption of a very small group of cells that make insulin. We have learned a great deal about how that process works and what cells are involved. Very recently, within the past year, one of our grantees discovered a specific amino acid, which is part of a protein—in the cell. This is just one little link in a chain, so to speak, that seems to confer either protection from or susceptibility to this disease.

So we do not have a cure, and we are not going to have a cure tomorrow. But we clearly are making progress in narrowing this disease process down to something that I think is beginning to make sense.

In the adult form of diabetes, we are not that close. We are dealing with a much different type of process which takes many different forms. We cannot at the moment sort of zero in, so we are trying to at least take specific approaches. We are trying to take advantage of very new, modern genetic mapping techniques in terms of getting clues for a much more specific approach.

One of our colloquia that I mentioned previously in terms of the proposed interdisciplinary centers was held specifically to try to address this question.

CYSTIC FIBROSIS CENTERS

Senator CHILES. The committee provides $3 million to fund cystic fibrosis research centers through the competitive process.

How many centers have been funded, and what progress is being made on cystic fibrosis research?

Dr. GORDEN. If I could take the second part first; cystic fibrosis is one of the areas where we see how progress essentially rides on the wings of technology. It has suddenly taken off because the technology has now progressed to a point where we can begin to go look specifically for the genetic defect.

Of all the myriad of genes, there is one particular gene that is abnormal in cystic fibrosis, and scientists are very close to identifying that gene. That will be a major advance. That gene will tell us which specific protein is diseased in the cells of the cystic fibrosis patients, which will in turn give us an understanding as to why this clinical picture emerges.

I think this area is one where tremendous progress has been made in the last several years and where we can really see a certain light at the end of the tunnel.

We, along with the National Heart, Lung, and Blood Institute, plan to fund several cystic fibrosis centers in this fiscal year. We have those applications in. I do not know exactly how many because it will depend, to some extent, on the size of the particular center applications and their quality. We expect to complete that review in the next 6 weeks to 2 months, and we certainly expect to make awards within this fiscal year.

### GALLSTONES

Senator CHILES. Currently, about $2.5 billion is spent on treating gallstones. The Institute has funded research at the Mayo Clinic, which has developed a nonsurgical treatment for gallstones, eliminating the need for surgery.

I understand it is still experimental, and many health insurance plans will not pay for it. At what point will this be beyond the experimental stage, and what additional efforts are needed by the Institute to reach that stage?

Dr. GORDEN. This technique that you refer to is the injection of a solvent into the gallbladder which actually dissolves gallstones, in conjunction with a drug that the Institute sponsored studies on previously, that is, a drug that will hopefully then prevent the reformation of gallstones.

This technique was developed, as you say, by scientists at the Mayo Clinic. We think that there is a great deal of promise in this technique. It is still experimental in the sense that we are not sure that it is ready for full-fledged clinical application and I think it needs a longer period of followup, but there is a great deal of promise.

In addition, the technology that was first used for kidney stones, the lithotripsy device, that crushes kidney stones with shock waves, is now being used or introduced for the same type of effect on gallstones, and we are going to be watching that very closely. We are not sponsoring that particular research right now, but industry is interested in getting this type of therapy into production and is sponsoring it. We are watching it very closely.

If there is a need for us to enter into this area, we certainly will because we think it has a great deal of promise. We think that the solvent technique, the drug technique, and the lithotripsy technique are all going to be very important applications for the treatment of gallstones in the future.

### ORGAN PRESERVATION

Senator CHILES. Last year an Institute grantee at the University of Wisconsin developed a new process that preserves organs for transplantation. I understand it has been used on 60 livers and has kept them viable for up to 20 hours, instead of the previous maximum of 6 to 8 hours.

Does it look like that process will work with other organs?

Dr. GORDEN. It has been used primarily with the liver, but the principles involved in preservation should be applicable to other organs, and they are certainly interested in exploring the question of its general applicability. There is no reason to believe that there is anything specific about liver tissue. The technique really has to do with cells in general and their ability to undergo lower temperatures and still remain viable, so we think it will have applicability to other tissues.

Senator CHILES. How soon do you think that you will begin to be beyond experiments?

Dr. GORDEN. I think in the next year or two it may have much more general clinical applicability.

Senator CHILES. Can you tell me why the Chicago cystic fibrosis center is being closed?

Dr. GORDEN. I am not aware of a Chicago cystic fibrosis center. We certainly do not fund one. I do not believe there is an NIH center——

Senator CHILES. I heard something on the House side. We will get back to them.

Dr. WYNGAARDEN. I think that is the sickle cell center which is funded by the National Heart, Lung, and Blood Institute. That Institute has a legal requirement to fund 10 centers, and these compete through peer review periodically all at once. They are all on the same 5-year cycle. This year there were a considerably larger number than 10, and in the scientific review process, the Chicago center was one of the lower ones. The council, in the final recommendations, recommended another center instead because of a series of programmatic issues. They try to have as much diversity in the centers as possible, and while the Chicago center was very highly regarded, it is also very well funded from other sources. So it was one of those decisions that was based on the availability of funds and the peer review system and the judgment of the council in the final allocation.

We have been working with the Chicago center for interim funding and alternative arrangements through the peer review system, perhaps the center could be funded with a research grant or some other mechanism.

Senator CHILES. Dr. Goldstein, we are ready to talk about stroke.

## NATIONAL INSTITUTE OF NEUROLOGICAL AND COMMUNICATIVE DISORDERS AND STROKE

Dr. GOLDSTEIN. I thought you were going to ask me about sickle cell.

Senator CHILES. I switched.

Dr. GOLDSTEIN. Mr. Chairman, we are just beginning to realize the benefits of this committee's generous support of basic neuroscience research. We are in the stage where, in fact, new knowledge gained from basic research is now being applied to the clinical problems of the brain and other human tissue. For example, the nervous system is particularly sensitive to genetic defects during its developmental period. Recently, scientists have isolated demonstrated the gene which, when defective, is responsible for the most common form of the muscular dystrophies, known as Duchenne muscular dystrophy. That gene has now been identified with the cooperation of the outside community, namely, the Muscular Dystrophy Association of America. Not only has that defective gene been identified, but the gene product whose absence results from this defective gene, is now known. It is a protein called dystrophin. Now that we know the specific protein which is absent in the disease, we can begin to figure out why muscles deteriorate in this devastating disease of young people that leads to disability and often death, and to propose avenues of treatment to prevent or correct muscle destruction.

I was telling Dr. Wyngaarden this morning that we have learned about certain mice with a form of dystrophy that have exactly the same genetic defect. During the mouse's early stages, its muscles begin to degenerate. But then this particular strain of mice overcomes the defect naturally and grows to maturity with no muscular disease at all.

Quite obviously this is very interesting to us. We want to know what that mouse knows that we do not know, and we are working hard to learn. So genetic diseases of the nervous system have become a very important focus of our research. The rapid expansion of our understanding of neurogenetic disorders has been built upon the new technology that is now available to us.

As an aside, we are investing a great deal of money in bringing that new technology to the attention of young clinicians during their training period. We are encouraging them to use that technology in clinical research, to be aware of the advances and opportunities emerging from basic neuroscience research, and to bring this new knowledge to the clinic.

Senator CHILES. Give me, if you can, just some kind of a road map of what you see happening with the muscular dystrophy now. Where will it go from here?

Dr. GOLDSTEIN. Where will the research go?

Senator CHILES. I know you cannot be exact.

Dr. GOLDSTEIN. Let me dream with you, if I may.

The absence of the protein dystrophin may result in the destruction of muscle. Two or three areas of research are now unfolding. First, and this is probably going to be the longest most difficult area, is to understand the normal function of dystrophin and how we can replace the protein or substitute for it with something that would perform its function. That will probably require techniques of genetic engineering, and answers are way in the future.

The second area of research focuses on that unusual mouse. What chemical is that mouse producing that offsets this particular protein? Can we identify that chemical? I am going to guess we can.

Once having identified it, we face the third and very difficult question, namely, how do we get that chemical into every muscle in the body without injuring the bodies vital organs?

So that is where we are in muscular dystrophy research. And we are going to win. When will we win? I do not know. But this is an exciting field of research. It is hot. It is catching a great deal of attention; and particularly younger investigators are changing their avenues of research to enter this area because there is hope and there is a lead.

So I do not know when the answer to muscular dystrophy is going to happen, but it will happen.

The interesting thing is that the new methodology also opens up so many other genetic diseases of the nervous system, like neurofibromatosis. About 20 percent of all cases of Alzheimer's disease we know are familial and probably based on a genetic defect; that area is opening up thanks to these new research approaches.

So with this methodology, scientists are moving on at a very excellent pace toward a better understanding of nervous system disorders.

We are putting a lot of effort into this research because it does have promise for clinical application in the reasonable future; it is not just a laboratory experiment.

The second disorder I would like to address, sir, is, in fact, stroke. We presently have four clinical trials going on in stroke. Two are testing, pharmacological ways to protect the brain when blood flow is reduced and the brain is deprived of oxygen and sugar. This is the period when the brain is really most vulnerable.

Senator CHILES. With the onset of the stroke?

Dr. GOLDSTEIN. Just as the stroke is occurring. How can we step in pharmacologically right there and protect that brain until recirculation of blood flow to the brain occurs? The events that happen during that first 6 hours following a stroke probably determine the permanent effect of the stroke on the brain.

So we are trying these two chemicals in humans because we have some hope that they can protect brain cells during that acute period immediately following a stroke.

### CAROTID ENDARTERECTOMY CLINICAL TRIALS

We have two other trials going on that involve a surgical procedure called carotid endarterectomy. In this procedure the surgeon removes fatty deposits from an artery in the neck that feeds blood to the brain. Approximately 100,000 of these procedures were done in the United States last year. And sir, we have no scientific evidence proving that the procedure does one bit of good.

The issue is, it has become part of our medical armamentarium. Therefore, we have decided the time has come to evaluate carotid endarterectomy in a clinical research setting. And 16 institutions in this country and others in Canada have banded together to do these two controlled clinical trials. These are very difficult trials to do because carotid endarterectomy has become part of our usual medical practice. Physicians are very concerned that their judgment is being questioned. This has been going on, by the way, since 1953.

Senator CHILES. What has been going on since 1953?

Dr. GOLDSTEIN. This surgical procedure. It was first performed in this country in 1953, and is now among the most common surgical procedures in the United States. So during this past year we have begun two separate trials to evaluate the risk-benefit ratio and develop guidelines for patient selection.

Senator CHILES. But you say there is no evidence that that surgery is doing any good? In other words, you know, I am a lay person asking a person, but an angiogram shows that you have got a coronary blockage to a couple of arteries, and generally speaking, let's say,if you have got two that are totally blocked or about totally blocked, there are not many doctors that will not say you had better do something about that. When you get into partial, then you get into those.

If you have got a blockage, a total blockage, there is still no——

Dr. GOLDSTEIN. Sir, this may surprise you.

Dr. WYNGAARDEN. Senator, was your question about coronary blockage?

Dr. GOLDSTEIN. This is an analogy.

Senator CHILES. I know I am talking about two different things.

Dr. GOLDSTEIN. Let me go to a real extreme, and this will surprise you. There are four major blood vessels feeding the brain. In a number of cases on record all four blood vessels were completely occluded, stopped up, and the person did not know it. This was possible because of collateral circulation. When blockage of the major vessels occurs slowly, the network of collateral arteries may protect the brain by providing alternate routes of blood flow. This is fairly rare, but I am using it to make a point.

What troubles us is that when we are dealing with an impending stroke, which we call a transient ischemic attack, the symptioms are brief and easily overlooked. For example, a person may wake up in the morning and his hand is not quite working right; he thinks he slept on it, shakes it off, and 5 minutes later he feels perfectly fine. So he ignores the problem. That is a transient ischemic attack. In fact, it is a medical emergency because the patient is beginning to experience the first symptoms of stroke.

The traditional response—and it seems to make perfectly good sense, as you have said, has been, to do an angiogram, find there is a partial occlusion in a blood vessel supplying the brain, open up the carotid artery in the neck, and clean that blood vessel out.

There is no scientific indication at all that cleaning that blood vessel out, in fact, prevents stroke. The incidence of stroke following carotid endarterectomy in a 3-year period in the same brain hemisphere appears to be identical whether you do or do not have the surgical procedure.

Now, I have got to be very careful because I have just displayed my own bias. Let me rephrase that.

We think that in some patients this procedure probably is efficacious. The question is, what are the characteristics of those patients? Are there

100,000 such patients each year who need this procedure? That is what we are trying to find out because in other advanced countries—England, Canada, France, West Germany—the number of carotid endarterectomies per 100,000 patients is a great deal less than we do in this country. What we are trying to find out is not only whether carotid endarterectomy is useful or not useful, but in which patients is it useful, rather than having it become, as it is now, a generally acceptable procedure done for all transient ischemic attacks for nearly all patients.

And so these trials have been launched. We are having some difficulty recruiting physicians who will say yes, I am willing to let a computer decide that this patient will have the surgery along with the best medical treatment, while another patient will receive identical medical treatment but no surgery. In 3 years I hope I can answer the question, for the public good: Under what conditions do we use carotid endarterectomy, and under what conditions do we not?

### HEARING AIDS

If I may move on, I thought you might be interested in what a modern hearing aid looks like. This one is state of the art. That includes the batteries, Senator Chiles. It is only about the size of a dime, but it includes batteries, microphone, amplifier—the whole thing. I thought you might be interested.

Modern Hearing Aid

It was perfected in southern Florida. It can now be bought in any hearing clinic, and we hope it is being used widely.

Senator CHILES. Sells for $50?

Dr. GOLDSTEIN. No, sir.

It is fairly expensive. This is an example of modern technology being applied to hearing loss.

Senator CHILES. Let me ask you this. As a person that shot a shotgun too many times, and was a cannon cocker in the artillery, you notice, of course, you lose your highs. When I get into a cocktail party or something, I hear a heck of a lot of noise. I just do not hear what anybody says. So I am nodding my head and hope they are not telling me their sister died. [Laughter.]

And yet, when I talk to most of my friends who wear hearing aids, they say it only accelerates that problem, that they still hear twice as much noise, but it has not done anything for their highs.

With our technology, are we doing anything to replace, not amplification, but to replace what the loss is?

Dr. GOLDSTEIN. Sir, I was a tank gunner in World War II, so I know exactly what you are talking about. When that cannon went off the noise inside the tank made our eyeballs go back and forth.

So my high tones are pretty bad. My wife points that out to me.

Let me answer your question in two separate ways.

First of all, one of the problems that you and I have is background noise.

Senator CHILES. Right.

Dr. GOLDSTEIN. When you and I are talking in ordinary conversation, we are only interested in hearing the person we are talking to; background noise from things that are happening around us distracts us and we want to avoid hearing that. On the other hand, when we are at a concert we want to hear the distant sound coming from the stage, and not hear the closeup sound of the person next to us whispering. This is a difficult task for a hearing aid to handle, but progress is being made in the development of what are called intelligent hearing aids that will do the job. By flipping a little switch, we would be able to tune the hearing aid to get rid of the background noise while we talk to each other, or get rid of the close sound while we enjoy a concert.

Senator CHILES. Now you are talking.

Dr. GOLDSTEIN. We are working on this. I thought 4 years ago, when we first started trying to develop this, that with modern electronics the answer would be right around the corner—why can you not do this? Well, it has been 4 years, and my staff still is explaining to me why it is so difficult. It is a tough job to accomplish, because the issue is how much of the background noise do you tune out before you seriously interfere with local communication. And it is that marginal area, that grey zone between background noise and direct communication, that has to be solved.

But experts in many disciplines of the neurosciences and communicative sciences are working on that problem.

Now, you have asked, really, the $64 question, namely, can we get rid of all these devices? Is there some way we can manipulate the brain to increase the hearing perception of those who have partial hearing loss? There is now a device to help people who have complete hearing loss; it is called a cochlear implant.

Do you know about the cochlear implant?

## COCHLEAR IMPLANT

Senator CHILES. I think I have heard something, but I do not know much about it.

Dr. GOLDSTEIN. Our ear has three sections. The inner ear, the innermost section, is where the nerve cells are that transform mechanical waves into electrical impulses. These impulses get transmitted into the brain by the auditory nerve and the brain interprets them as sound. The end of that auditory nerve has very fine hair cells, and it is those hair cells that transform the mechanical energy into electrical energy. With constant trauma from loud noise, such as rock music, or the guns of a tank, or being a hunter, or just getting older, those hair cells die and disappear, and it depends on which hair cells disappear whether you get high tone loss or low tone loss.

As another example, children born to mothers who have German measles during pregnancy may become profoundly deaf because all the hair cells have been destroyed by the German measles virus.

There is now a device called a cochlear implant in which a very fine wire is surgically implanted inside the inner ear to stimulate the auditory nerve, bypassing any remaining hair cells. Then a very tiny receiver is implanted underneath the skin near the ear. Electrical waves hit the receiver, and with a little electrical charge, are transmitted to the wire, and so—and I am using hyperbole—the deaf can hear again.

Now, we are uncertain about what they really hear. What they may hear is what you and I would perceive as static. We have not yet learned how the brain takes the electrical energy and understands it as sound, as voice, as music. We do not know how the brain does that yet.

As we continue to study this phenomenon we will probably learn how the brain performs this feat, and then we may be able to find ways to help those who have not been completely deafened but have different types of hearing loss—loss of high tones, as an example. But at the moment we do not have any insight into what is going on inside that piece of the brain called the auditory cortex.

I have gone around your question. I really did not answer it, and I know I did not.

## INTERAGENCY COMMITTEE ON HEAD INJURY

Senator CHILES. Well, you told me what you could try to tell me. It ain't there yet.

Dr. GOLDSTEIN. It ain't there yet, but we are working.

Finally, Mr. Chairman, a word about head injury. This committee asked the Secretary of the Department of Health and Human Services who has assigned the responsibility to our Institute, to organize an interagency committee on head injury, and gave it two charges. The first charge was to review the status of research on head injury and the head injured, and come up with recommendations pertinent to needs and opportunities in the area of research. The second charge was to look at the health care system which is providing health care to the head injured, to identify the clinical services needed during periods of acute and chronic injury, and to recommend to the Secretary and to the Congress how we as a Nation can meet these needs.

The committee has been organized. Thirteen Government agencies are now represented on the committee, including the Veterans Administration, the Department of Education, NIH, and the Department of Defense, and we have already started our activity. I have the privilege of being the chairman, and I can assure you, sir, that next year when your successor is sitting there, we will be able to hand him that report describing what we consider our Nation can and should do about the issues of head injury research and clinical care.

May I say that last night there was a wonderful program on public broadcasting called "The Journey Back," and it is the story of the head injured and what happens to these people. If you have the opportunity when it is rebroadcast, as I am sure it will be, I would advise you to see it. "The Journey Back" was a most informative and touching story of a number of young people who have been head injured, who go into coma, and what happens to them while they are in coma. Some of them appear to be in coma and hear everything that is going on in the room; others are in deep coma and do not. The program shows what happens to them after they come out of the coma—their language deficits, the way society quite often rejects them. It is a very touching story on public broadcasting, and I would strongly recommend it. You would find it very informative.

I have just touched on items. The committee has asked for, and I know you have received, a copy of this report, "The Decade of the Brain," which was prepared by the NINCDS National Advisory Council at the Congress' request. This has been, I am sure, distributed. It describes, in much greater detail than I can here, the current status of research in the basic and clinical neurosciences and communicative sciences, and what are the opportunities.

PREPARED STATEMENT

Mr. Chairman, excluding AIDS, the President's budget for 1989 requests $557.5 million for the NINCDS.

I would be delighted to answer any of your questions.

[The statement follows:]

# STATEMENT OF MURRAY GOLDSTEIN

For more than 30 years, the National Institute of Neurological and Communicative Disorders and Stroke (NINCDS) has conducted and supported research on brain structure and function and some 650 disorders of the central nervous system and senses of communication. While a considerable portion of the Institute's research initiatives has focused on the nervous system's fundamental workings, clinical scientists have been rapidly advancing our knowledge of convulsive, communicative, developmental, and neuromuscular disorders, as well as diseases characterized by demyelination, atrophy, hearing loss, and dementia. Several stroke intervention studies are testing the effectiveness of drugs and surgical treatments to improve the long-term outlook for patients at risk of this disorder. Cochlear implants that stimulate the auditory nerve in the profoundly deaf utilize electronic circuits that are becoming more sophisticated, permitting deaf individuals to make finer distinctions between different auditory sounds. Two new clinical trials are evaluating drugs that alter the levels of brain chemicals reportedly depleted in Alzheimer's patients. Drugs that inhibit the metabolic action of harmful enzymes are under study for their effectiveness in treating parkinsonian patients. Finally, four drugs evaluated through the NINCDS antiepileptic drug development program have been marketed and are now widely used.

Investigators are exploring techniques for replacing enzymes that are missing or reduced in patients with developmental disorders of the brain such as Tay-Sachs disease. Studies concerned with genetic-metabolic disorders affecting the nervous system are expected to provide crucial information about the etiology and pathogenesis of Batten's disease. Yet other investigators are exploring whether the lack of chemicals called nerve growth factors are responsible for motor neuron death in amyotrophic lateral sclerosis. If this disease is caused by the loss of such factors, physicians may eventually be able to treat the disease by providing these to patients in much the same way that they provide insulin to diabetics.

As part of the national effort in progress on AIDS, the Institute is focusing research attention on how the AIDS virus so dramatically impairs nervous system function. We now know that the nervous system and the immune system are the two primary targets of AIDS virus infection. At least 70 percent of all AIDS victims have serious nervous system involvement; the percentage may be as high as 90 percent. Studies are being conducted to determine the route by which the AIDS virus infects the various elements of the nervous system. Detailed clinical studies have been started to identify the complete spectrum of neurological involvement, as are studies to identify potent drugs capable of crossing the blood-brain barrier and destroying the virus inside the nervous system.

Genetics has begun to provide important discoveries of markers, links, and tests for genetic disorders of the nervous system. Among the brain disorders for which scientists now have new information are Huntington's disease, Duchenne's muscular dystrophy, and Gaucher's disease. Work is proceeding to validate genetic markers for the two separate but somewhat similar disorders known as Neurofibromatosis-1 and Neurofibromatosis-2, which will ultimately make possible prenatal diagnosis and accurate genetic counseling. Further research is leading to the isolation of genes of other neurological diseases, such as Alzheimer's disease and myotonic muscular dystrophy, and to the discovery of the nature of the biochemical defects that these genes control.

A glimpse of work under way in laboratories and clinics around the country shows why leading investigators believe we are opening a new era in the study of the neurological and communicative diseases. Recent findings are beginning to suggest a possible widespread involvement of retroviruses in chronic neurological diseases, many of which are currently of unknown origin; an example is multiple sclerosis. Scientists have linked a class of retrovirus related to HTLV-I to tropical spastic paraparesis, a common paralytic disease of the tropics. The virus, which is characterized by the development of a progressive weakness of the legs and lower body, is the second retrovirus, after AIDS, to be linked to a degenerative neurological disease in humans. It is of interest that not all patients with multiple sclerosis or tropical spastic paraparesis show exposure to HTLV-I. This is consistent with the concept that these diseases may have very similar manifestations but multiple etiologies, one of which is related to HTLV-I or a closely related retrovirus.

The process by which HTLV-I might produce the symptoms of tropical spastic paraparesis remains a puzzle. One of the questions facing scientists is whether the virus that is linked to the neurological conditions is genetically and molecularly similar to the one that causes leukemia. Only two or three individuals have been found to have both tropical spastic paraparesis and leukemia. Studies are in progress to isolate and clone the virus from tropical spastic paraparesis patients so that it may be compared with leukemia-causing isolates.

Investigators have also raised the possibility that a virus related to HTLV-I may cause at least some cases of multiple sclerosis. Several researchers have found antibodies that react with an HTLV-I protein and have detected gene sequences in some cells of patients with multiple sclerosis that are related to HTLV-I gene sequences. This does not necessarily provide evidence of infection by HTLV-I, but suggests the possibility of an association with an as yet unidentified relative of this virus.

In order to follow up on these research findings, in November, the NINCDS issued a request for applications to establish up to four interdisciplinary research program projects to investigate the etiology and pathogenesis of retrovirus-associated neurological disorders. The Institute expects to receive proposals to study the apparent predilection of some retroviruses for the nervous system and is optimistic that this approach to the study of retroviruses will provide important new information on preventive and therapeutic strategies for such diseases as neuro-AIDS, tropical spastic paraparesis, and multiple sclerosis, as well as fundamental insights into the retroviral basis of these disorders.

An estimated 400,000 to 500,000 Americans suffer head injuries severe enough to cause death or admission to a hospital each year; although the number is unknown, certainly an equal number have head injuries that are thought to be less debilitating. Another 10,000 to 12,000 Americans are disabled by traumatic injuries to the spinal cord. The medical, social, and economic impact of these injuries are enormous, with specialized long-term care for paralyzed patients alone costing society approximately $2 billion each year.

As part of its effort to alleviate the personal tragedy and national burden of spinal cord injury, the NINCDS is sponsoring a multicenter randomized double blind study with drugs to ameliorate paralysis after injury. Five NINCDS-sponsored Spinal Cord Research Centers are conducting research to enhance our understanding of the events that happen in the interval between spinal cord injury and the death of nerve cells--an interval that may be as long as 24 hours, a window during which effective treatments may result in the prevention or amelioration of paralysis. Scientists are attempting to identify the biochemical events that occur subsequent to spinal cord injury and develop interventions that will prevent or lessen the resulting damage, thereby improving the patient's chances for a favorable outcome. Finally, greater attention to research on the restitution of function for the spinal injured patient is being vigorously pursued.

Functional neuromuscular stimulation is a promising neural prosthetic technique to aid spinal cord-injured patients. It involves implanted electrodes passing current into paralyzed muscles to stimulate movement and sensation. Investigators are developing probes that can intercept electrical impulses to the brain, reroute them around damaged nerves and deliver them to the appropriate muscles. Similar probes will pick up sensations from the paralyzed limbs and relay information back to the brain, creating a "closed loop" that permits patients to order a limb to move and then know how it responds. Already an elementary electrode implant system has restored a form of hand grasp that allows a paralyzed patient to resume everyday tasks such as combing his hair, drinking from a cup, and writing with a pen. Also under study are artificial sensors that can be worn like a glove to reinstate a sense of touch. Eventually the sensors will be miniaturized, allowing implantation beneath the skin of the finger tips.

Traditionally, scientists believed that damaged nerve cells in the brain were incapable of regeneration. However, recent work shows that under special laboratory conditions these damaged nerve cells may be able to function again. Researchers have demonstrated that nerve cells from the mammalian central nervous system sprout new branches when they are in contact with the supporting cells associated with skin and muscle nerves, thereby showing that adult brain cells have the capacity for growth. Whether this property can be used to repair the injured brain with its billions of nerve cell connections is a subject of ongoing research.

Recent studies have also shown that in some cases implanted embryonic nerve cells appear to connect with other nerve cells and restore disrupted functions. Available evidence suggests that there are at least three ways by which implants may act to restore function. First, they may provide a source of appropriate neurotransmitters that replace those depleted from the host tissue as a result of any number of pathological conditions. Second, the implants may replace degenerated neuronal populations in the central nervous system and, thereby, assist in the reconstruction of damaged synaptic circuitries. Third, the implants may form cellular bridges that facilitate nerve cell elongation across injured sites.

Whereas vigorous intensive-care monitoring and early treatment of organic and biochemical dysfunction in patients with head injuries have led to improved survival, many of these patients are not returned to useful lives. Thus, the research challenge now includes both understanding the mechanisms that lead to improved survival and understanding the biochemical activities that will lead to improved cerebral function. Although the studies are still at the earliest stages of investigation and development, promising leads have been obtained in the experimental use of neural transplants to aid in the recovery of the injured nervous system. In the next few years, it may be possible to replace tissues damaged by injury and restore at least some of the functions for which the damaged tissues were responsible.

Nearly 2 million Americans are either totally deaf or suffer such significant hearing loss in both ears that they cannot hear conversation, a phone ringing, traffic noises, or a fire alarm. Another 14 to 15 million are moderately to severely impaired. New and sophisticated techniques are providing an increasing number of answers about the molecular organization of the hearing system that will eventually help in understanding how to prevent or treat many of the disorders of hearing. Fundamental to this understanding are neurochemical analyses of the structures composing the hearing mechanism and the identification of the neurotransmission between auditory nerve cells. Both basic and clinical research directed at understanding the biology of hearing and the mechanisms of hearing loss will ultimately provide the answers to as yet unanswered questions, and in turn will offer a more promising future for those afflicted with hearing disorders.

The discoveries and insights I have presented today provide unprecedented opportunities for scientific advances on the brain and nervous system. Modern research, however, is more demanding to its investigators than ever before. It requires complete dedication of effort, the best possible facilities and equipment, and the constant influx of highly talented, well-trained young minds to sustain the creative energy that characterizes any serious scientific endeavor. The Institute recognizes the benefits to be achieved through a strong and comprehensive research program in the neurosciences and communicative sciences and is making every effort to maintain the momentum of support for these activities.

Mr. Chairman, the FY 1989 budget request for this Institute is $557,585,000. I will be pleased to answer any questions you might have.

# BIOGRAPHY OF MURRAY GOLDSTEIN

October 13, 1925, New York, New York

EDUCATION: B.A., New York University, 1947; D.O., Des Moines Still College of Osteopathic Medicine, 1950; M.P.H., University of California, School of Public Health, 1959; Mayo Clinic (Neurology), 1968.

PROFESSIONAL HISTORY: Director, NINCDS, 1982-present; Acting Director, NINCDS, 1981-1982; Deputy Director, NINCDS, 1978-1981; Medical Officer, Commissioned Corps, PHS (Assistant Surgeon General), 1953-present; Director, Stroke and Trauma Program, NINCDS, 1976-1978; Director, Extramural Programs, NINCDS, 1961-1976; Visiting Scientist, Mayo Clinic and Graduate School, Rochester, Minnesota, 1967-1968; Chief, Special Projects Branch, NINCDS, 1960-1961; Assistant Chief, Research Grants Review Branch, DRG, 1959-1960; Director, Epidemiology and Biometry Training Grant Program, DRG, 1956-1958; Assistant Chief, Grants and Training Branch, NHI, 1953-1958; NIH Representative, DOE Interagency Committee on Handicapped Research, 1982-present; Member, DHHS Task Force on Alzheimer's Disease, 1983-present; Chairman, DHHS Interagency Committee on Spinal Cord Injury, 1986-1987; Commissioner, DHHS National Commission on Orphan Diseases, 1986-present; Chairman, DHHS Interagency Committee on Head Injury (1988-present).

PROFESSIONAL ORGANIZATIONS: American Academy of Neurology; American Association for the Advancement of Science; American Heart Association, Council on Stroke; American Neurological Association; American Osteopathic Association; Association for Research in Nervous and Mental Disease; Member, Board of Directors, John P. Robarts Research Institute, London, Ontario, Canada; Society for Neuroscience; The American Parkinson Disease Association, Medical Advisory Board; Eisenhower Institute for Stroke Research; United Cerebral Palsy Research & Educational Foundation, Board of Directors; Consultant (Neurology), Pan American Health Organization; Consultant, World Health Organization Program on Neurosciences; Chairman, World Health Organization Task Force on Cerebrovascular Disorders; World Federation of Neurology; International Brain Research Organization; Commission on Alternative Health Care, U.S. Olympic Council on Sports Medicine.

HONORS, AWARDS: Beta Alpha Epsilon, Biology National Honor Society, NYU; Psi Chi, Psychology National Honor Society, NYU; Sigmi Alpha, Osteopathic Scholarship National Honor Society, College of Osteopathic Medicine; Delta Omega, Public Health National Honor Society, University of California; Doctor of Science (Hon), Kirksville College of Osteopathic Medicine; Doctor of Laws (Hon), New York Institute of Technology; Doctor of Science (Hon), University of New England; Doctoris Honoris Causa, Medical University of Pecs, Hungary; Doctor of Science (Hon), Ohio University; Certificate of Merit, American Neurological Association; 2nd Vice President, American Neurological Association; Silver Star, Purple Heart, U.S. Army; Meritorious Service Medal, Public Health Service; Distinguished Service Medal, U.S. Public Health Service; Founders Day Medal (S.S. Still Medal), University of Osteopathic Medicine and Health Sciences, Des Moines, Iowa; Patenge Medal of Public Service, Michigan State University.

## HEARING INSTITUTE

Senator CHILES. We have talked some about what is going on in hearing. As you know, the NIH reauthorization legislation introduced a few weeks ago would create an Institute for Deafness Research.

Tell us what priority you are giving that now, how this would change things, and is it desirable to create a special Center for Deafness Research, and if such a center was to be created, should speech go into that as well?

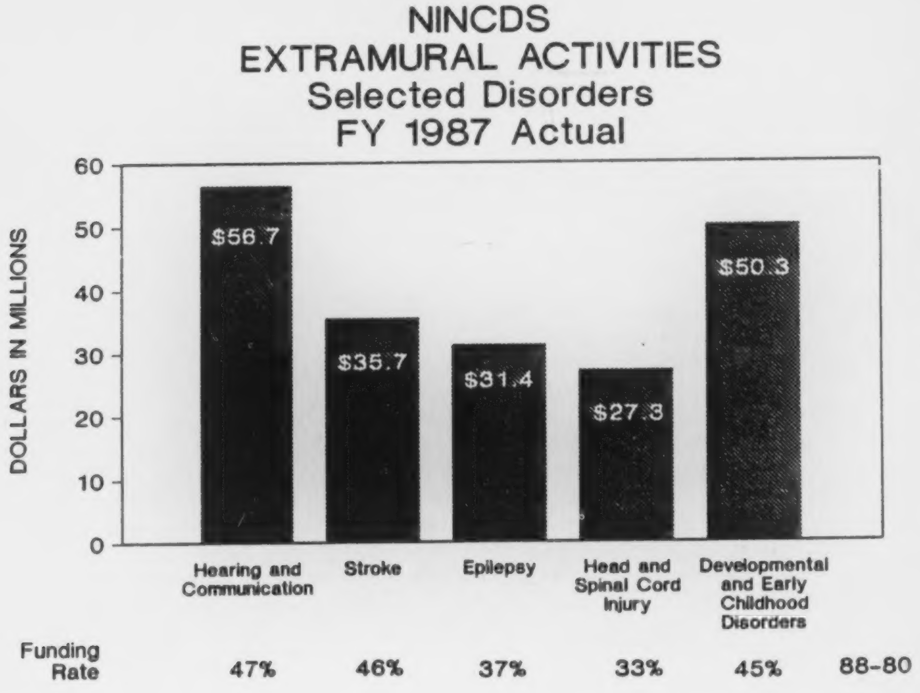
Dr. GOLDSTEIN. I will ask Dr. Wyngaarden to help me with some of those questions since he is the policy expert.

Dr. WYNGAARDEN. I will yield you my time. [Laughter.]

Senator CHILES. It does not sound like Calhoun wants the ball.

Dr. GOLDSTEIN. Hearing research, or hearing and deafness research, receives the second largest proportion of the NINCDS appropriation. The first largest proportion is basic neuroscience. The second is hearing. The third is developmental defects in children. The fourth is stroke.

What I am really trying to say, sir, and I just happen to have a chart here for you, is that hearing research is one of the top priorities of the NINCDS in terms of its research activity. What more can I say, other than we think hearing and deafness is a very important problem and are investing more funds into hearing research than we are in research on stroke, epilepsy, or head and spinal cord injury. Hearing research has long been one of our top priorities.



This reflects the importance of hearing loss as a national health problem. And we obviously believe it is an important subject. Is there additional research that can and should be done? Of course there is, just as there is more to be done in stroke or epilepsy or head injury. It is a question of the distribution of available resources among all these areas of high priority.

In the NINCDS, the research program on hearing has divisional status. That means it has top status, and the Director of the Division of Communicative and Neurosensory Disorders reports directly to me. He is an otolaryngologist, former chairman of the Department of Otolaryntology at the University of Chicago. He has his own advisory panel of experts.

What I am really trying to say is that administratively we have also given research on hearing top priority.

What would establishing a new institute accomplish? Now I display my bias. Scientifically, I do not think it would make any difference at all. I do not think having a new institute will either increase or decrease the amount of research. I frankly think it is a public relations and administrative issue, and not a scientific issue.

That happens to be my own personal opinion. I do not know if Dr. Wyngaarden or the Secretary agrees.

Dr. WYNGAARDEN. I might add a few words, Senator Chiles. NIH has historically not championed these moves to create new administrative units, and I think it reflects what Dr. Goldstein says, the conviction that scientifically these are usually not essential splits due to emergencies or to new fields of interest or prominence, but they have great public appeal.

We are concerned about the proliferation of administrative units. We are now negotiating 18 separate budgets each year with the Department and with Congress. We have 12 Institutes and six operating divisions that have their own funds. Last year we received two more administrative units; that is, the Nursing Center and the Arthritis Institute. This year we have heard about a hearing center, and the question of rehabilitation which you asked about the other day.

It seems there are a few more each year. They are not all successful, but there is a trend at the moment toward each group trying to seek its own center, its own area of recognition. The feeling that many of the doctors have is probably one of competition, to make sure one's own discipline is recognized, and behind it is the expectation that a new unit means more funds.

That has sometimes happened and sometimes not happened. We have examples of where a new institute is created and the program is probably less well off than it was under the umbrella of a larger organization with more flexibility in it. Each new unit also diverts funds from research to administrative costs for a new institute or center. Approximately $3½ to $4 million could come out of the research budget.

A hearing institute or center is superficially an issue of great appeal, particularly after the Gallaudet event. It is probably inevitable. But I think Dr. Goldstein has given a very sound argument, that from a scientific point of view, the issue is not whether it is part of the Neurology Institute or a separate organization. It is really a question of what its priority is and how much additional funding it is going to have. If it is going to double or triple the budget for hearing, that would be a good thing. If it is the same, it will not make any difference.

### NERVE REGENERATION

Senator CHILES. Last year, Dr. Goldstein, the committee directed the National Institute, your Institute, to expand its efforts on paralysis and spinal cord research, and $1 million was made available for that.

Please tell the committee what you have done in response to this request, and are there prospects for advances in the regeneration of the spinal cord?

Dr. GOLDSTEIN. Well, we thought the $1 million was not enough to take advantage of all the promising research opportunities, so we increased it by $1.8 million and took moneys from other areas. So we have moved ahead, and are continuing to move ahead.

I must tell you, sir, that research on spinal cord injury and nerve regeneration presently involves about $30 million. So the increase was really a marginal increase. We are moving ahead.

Now, the problems that we face are two, scientifically. One is intervening in the acute period immediately after injury. As I indicated with stroke, within 4 to 6 hours of injury to the spinal cord, with what we presently are able to do, the future of the injured person has probably been determined. The central nervous system has an uncomfortable habit of, when it is traumatized, contused, or banged, such as it may be in an automobile accident, instead of repairing itself, it begins to destroy itself.

So a minor injury to the spinal cord sets up a cascade of self-destruction within the cord. We have a very intense research program going on addressing those first 4 to 6 hours after injury to try to determine how can we stop that self-destructive process dead. That is probably going to mean finding some means of treatment that can be done at the roadside or in the football stadium, and not waiting for the person to be transported to a tertiary care facility to begin treatment.

We have some leads in that area. We have had leads in the past, and every one of them has failed. But now we have new leads that we are pursuing. As a matter of fact, the research group at Gainesville, led by Dr. Paul J. Reier, are among the leaders in investigating how can we intervene during the acute phase of injury and stop the spinal cord's self-destructive process.

The second part of the problem is chronic injury—the person who, let me assume, is paraplegic. What is the hope of restoring that person's ability to walk? Rehabilitation is a very important issue, but rehabilitation accepts that the paraplegic has lost the ability to walk and concentrates on helping that person use his or her other facilities. There is a very large research effort going on in that area. But what we at the

NINCDS are addressing is the question of how do we restore biologically the function that you have already lost. Can we make damaged nerves in the central nervous system—the spinal cord and brain—regrow and restore function?

Now we are dealing with very basic biology as to what does that nerve cell do in the central nervous system. We know that an injured nerve cell in your arm regrows. I can cut a nerve cell in your arm, and it will regrow and reconnect correctly withother nerve cells, and you can use your fingers again. Why does that regrowth not occur in the brain and spinal cord? It should be able to. As a matter of fact, damaged nerve cells in the central nervous system do try to regrow. They start to regrow, and something stops them.

That is a problem we are working on.

Will we find a way to promote and sustain nerve cell regeneration? I think so. When? Like with muscular dystrophy, I do not know.

Those are the leads we are pursuing.

Senator CHILES. So we are really literally talking about rejuvenation?

Dr. GOLDSTEIN. Yes, sir.

Senator CHILES. Well, you know, I did get a briefing at the University of Florida on some of the work that they are doing, and they sure have a lot of excited young people that are working in this area, if you want to talk about excitement. They certainly seem to be convinced that it can be done.

Dr. GOLDSTEIN. It will be done.

### BRAIN IMAGING RESEARCH CENTERS

Senator CHILES. During the last fiscal year you were funding 10 PET scan centers across the country. These are extremely expensive pieces of medical equipment to operate and are of great use in brain research.

How many of these centers does your 1989 budget fund?

Dr. GOLDSTEIN. Three.

Senator CHILES. Three in addition to the ten?

Dr. GOLDSTEIN. Three of the ten. We would be forced to drop seven of these brain imaging research centers.

Senator CHILES. What drove that decision other than dollars?

Dr. GOLDSTEIN. You have just answered the question, sir; it was dollars.

Senator CHILES. Well, that says something about the priority you place on these, then?

Dr. GOLDSTEIN. No, sir; it does not. It addresses the issue I think that chart addresses. The problem is now, with the funds available, do we maintain balance among all these different research fields. These brain imaging research center grants are all coming up for competition. They are not built into what we call the base; they are not our committed funds. They must compete for the new funds that will be made available by this committee and the Congress. We have to support research on hearing, stroke—altogether some 650 neurological and communicative disorders. When we look at the distribution of funds among all these important areas of research, we find we can support only three brain imaging research centers. In order to have four centers, I would have to cut the stroke projects. In order to have five centers, I would have to dip into funds for head injury and spinal cord injury research.

Senator CHILES. What will happen to the other seven centers?

Dr. GOLDSTEIN. One-half of them will close—just close—because they are so expensive to run. It is not a question of getting local funds.

Senator CHILES. That is what I am asking.

Dr. GOLDSTEIN. The other one-half will get local funding from their institution and will recompete for NINCDS support next year, hoping that funds will be available. But there are a few centers that will close. Sir, it is not because you are from Florida, believe me. I know the situation.

Senator CHILES. I do not know where they are.

Dr. GOLDSTEIN. There is one center in Miami that I do not think can commandeer local funds. That is also probably true for the one at UCLA. It is just that the situation locally is such that these centers would probably not get interim support to enable them to reapply for the 1990 budget.

### TISSUE PLASMINOGEN ACTIVATOR

Senator CHILES. Tell me just briefly, if you will, something about your TPA and what you are looking at now your new clot dissolving drug.

Dr. GOLDSTEIN. Oh, tissue plasminogen activator.

Senator CHILES. We professionals use these initials.

Dr. GOLDSTEIN. Oh. I thought it was a new Government agency.

Tissue plasminogen activator is a naturally occurring biological product which dissolves blood clots. It has been tried on the heart, and there is a controversy at the moment, as you know, about funding this for Medicare programs. Tissue plasminogen activator is one of the drugs that we are evaluating for use in stroke. We are trying to see if we can use TPA very early after onset of stroke, at the earliest symptoms, to dissolve blood clots in time to prevent further injury to the brain. That study is going on right now.

### BRAIN IMPLANTS

Senator CHILES. Tell me what are the prospects generally for repairing neurological damage and disease by implanting human tissue in the brain?

Dr. GOLDSTEIN. Let me use the example of Parkinson's disease which has attracted the most scientific attention. In animal experiments as high as the primate, at the NIH itself, in our own NINCDS laboratories, we have been able to completely restore function in monkeys with induced Parkinson-like symptoms by implanting animal fetal adrenal tissue into the brain.

So the biological experimental basis is there for the next step, namely, testing the implant in humans. In other countries of the world—Sweden, England, China, and Mexico that we are aware of—human fetal tissue has already been implanted in patients with Parkinson's disease. As you know, sir, this experimental procedure has not been done, as far as we know, in this country at this time.

The issue at the moment is one of ethics.

Senator CHILES. What have their results been where it has been used?

Dr. GOLDSTEIN. We do not know that yet. The research teams have not yet reported their results.

Senator CHILES. So we are right now with the ethics question?

Dr. GOLDSTEIN. Yes, sir.

Is that not fair, Dr. Wyngaarden?

Dr. WYNGAARDEN. Yes; we have a committee about to be formed at the request of the Department to examine this issue. We hope to do that as fast as we can, as I mentioned the other day.

Senator CHILES. I have to leave when the second buzzers come. We have started to vote, but maybe we can start, Dr. Shulman, with your statement.

## NATIONAL INSTITUTE OF ARTHRITIS AND MUSCULOSKELETAL AND SKIN DISEASES

Dr. SHULMAN. Thank you, Mr. Chairman.

As you know, we, too, have a very broad research mission with different diseases and areas to cover, as listed in the title of the Institute.

I would like to briefly share with you some of the advances and the opportunities research and activities this year, especially emphasizing those in which you and your committee have expressed an interest.

Let us first take a look at rheumatoid arthritis. The search for infectious agents as possible initiators of rheumatoid arthritis continues, and to pursue this further, we have already issued a program announcement inviting additional applications in this area. We hope to get some additional applications of high scientific merit to supplement ongoing research in this area.

This is also the 50th anniversary of the discovery of rheumatoid factor, which is an antibody that is very important in both the diagnosis and research on rheumatoid arthritis.

Lyme disease was recently called Lyme arthritis because that is the way it was first discovered. It is an increasingly important disease. It was first discovered in three small towns on the coast of Connecticut, and it is now spreading. It has now been reported in some 35 States and in six continents throughout the world. Our scientists have discovered that the cause of this form of arthritis is a spirochetal bacteria. It causes both an acute and a chronic, a late, arthritis. This late arthritis closely resembles the picture we see in rheumatoid arthritis itself.

So Lyme disease provides us with an unusual opportunity, a known microorganism, to find out how a microorganism can produce a chronic arthritis. This is a welcome challenge in our field at the moment.

When you take a look at the joint tissue under the microscope, you can find only a few of the bacteria, so therefore——

Senator CHILES. But it is a tick-borne disease.

Dr. SHULMAN. Yes, sir; that is another interesting story in and of itself, as to how this disease is tick-borne, and what might be done to prevent the spread of Lyme disease.

Senator CHILES. Can you cure Lyme if you find out?

Dr. SHULMAN. Yes, sir; you can cure the early phase of Lyme disease with antibiotics, recognizing it by its spreading skin rash and its early arthritis. We are, at present, uncertain as to whether or not we can cure the late manifestations of the arthritis.

Another challenge is that the new antibody test we have developed only picks up one-half of the early cases, so we need a better antibody test. However, Lyme disease can be diagnosed, Senator Chiles, by evaluating the patients whole clinical picture.

Senator CHILES. We had better stop here.

[A brief recess was taken.]

Senator CHILES. Go ahead, Doctor.

Dr. SHULMAN. Let's turn now to osteoporosis, which, is an area within our Institute of special research emphasis, and a major health threat. We have a great deal of research going on in this area. We have evidence that estrogen given to a postmenopausal woman can retard bone loss, and therefore, prevent hip and other fractures later on in life.

For the first time, two groups of investigators have discovered receptors for estrogen on bone cells. They have been trying to find these receptors for a long time and have now succeeded. This discovery opens up a whole new avenue of research in osteoporosis. We also have learned new information about the absorption of calcium which we can discuss a little later, if you wish to do so.

Epidermolysis bullosa, that terrible, tragic, disabling, blistering disease that affects children, comes in two forms, one an inherited form and the other an acquired form. Last year we reported to you that in the inherited form there is a defect in the anchoring fibrils, that is, the fibrils that keep the outer layer of the skin attached to the inner layer of the skin. Those anchoring fibrils are now identified as type VII collagen, a new type of collagen. This year there has been discovered an antibody in those patients with the acquired form, which is an immune mediated disease. The antibody is directed against the very same type, of collagen type VII as in the genetic form.

On the more clinical side, the epidermolysis bullosa registry that you asked us to create is now up and running. There are four clinical centers, and there is already an article describing the usefulness of the EB registry by Dr. Fine at Alabama in the current issue of the Archives of Dermatology.

The Lupus Erythematosus Coordinating Committee has completed its report and has submitted it to Congress. It is a substantive report.

Sjogren's syndrome is a disorder of middle-aged women characterized by dry eyes, dry mouth, joint disease, and other manifestations—it affects many different parts of the body. You requested us to develop a conference, and we have done so. We have organized and planned and will be convening a multidisciplinary conference. It will be called The Many Faces of Sjogren's Syndrome, and will include all the leaders in the field. It will concern itself with both basic and clinical research. The conference will be held at the Lister Hill Center on January 18 and 19 of the coming year, one day before inauguration day.

Low back pain is an area in which you have also expressed interest and requested a report. We have prepared such a report on low back pain research supported by the NIH; it was submitted to you earlier this year.

Our Institute in collaboration with the American Academy of Orthopedic Surgeons, has organized a high level workshop on new perspectives in low back pain research. This research conference will begin this Sunday for 4 days at Airlie House and will cover the many features of low back pain. Greatest interest has been placed in the intervertebral disc. However, the muscles and the nerves and the supporting structures of the spine are also very important, and these areas will be addressed at this conference.

The area of sports medicine and exercise pathophysiology is an emerging, new mandate for both our Institute and the NIH. Last year in April we issued a program announcement inviting more applications in sports medicine. We are very pleased to report to you that 52 new grant applications came from that program announcement, and that is a very interesting response.

We also held a scientific workshop last June on the injury and repair of musculoskeletal soft tissues. The proceedings have already been published; it is an important new document.

In the area of skin diseases, Dr. Wyngaarden reported in his testimony before you about the discovery that cyclosporin-A is very effective in severe psoriasis. This new finding is redirecting research toward immune mechanisms in psoriasis.

In the area of photobiology we have heard publicly as well as medically about a new wrinkle in skin disease research; actually, it is an antiwrinkle. All-trans-retinoic acid, called Retin-A, can reverse the wrinkling caused by sun, photoaging.

Senator CHILES. Oh, there is a tremendous amount of purchase of the Retin-A.

Dr. SHULMAN. It is difficult to get, I gather.

Senator CHILES. You almost had to get on a waiting list for a while, and of course, I know that their stock went up 10 points the first day.

Dr. SHULMAN. An interesting point about the trial that was reported in the AMA Journal by Dr. Voorhees at Michigan was that 92 percent of the people in the trial had to first get a rash, a dermatitis, before they got improvement, in smoothening of the skin, indicating what people will do in order to seek the fountain of youth.

Senator CHILES. That is right.

Excuse me. I have to go vote again.

[A brief recess was taken.]

Dr. SHULMAN. Just a couple of more points, Senator Chiles.

The first is that as requested, we have initiated the new Skin Diseases Research Core Centers Program this year. We sent out the announcement for the core centers in January, and had a deadline of March 25 for the receipt of applications. We have already received eight applications for these skin disease centers. The centers will be awarded this year.

Last, the new Institute has joined the effort in AIDS research. We have some very interesting new developments with respect to both skin disease, specifically psoriasis, and a young men's form of arthritis, called Reiter's syndrome. There is a very high frequency of AIDS in both of these disorders. These are reports from New York and from Tampa, at the University of South Florida, indicating a high frequency of these two disorders in AIDS patients.

We called a workshop on AIDS in December, sent out program announcements, and have already received some interesting new research applications in this area.

## PREPARED STATEMENT

Mr. Chairman, the 1989 budget request for this new Institute is $158,244,000. I would be pleased to answer any questions that you may have, sir.

[The statement follows:]

## STATEMENT OF DR. LAWRENCE E. SHULMAN

I am honored, once again this year, to have this opportunity to share with you several scientific advances that have been achieved this year by our extramural and intramural scientists in the fields of arthritis and musculoskeletal and skin diseases. I wish to discuss with you our new understanding of basic processes that underlie the numerous important diseases within our Institute's purview, and some plans for the future. The mission of the NIAMS includes support for multidisciplinary basic research and clinical investigations on a wide range of painful and disabling diseases that afflict the nation.

Last year I reported that research on rheumatoid arthritis had entered a phase of heightened productivity. It may now be possible to identify the risk of developing rheumatoid arthritis before symptoms develop. The marker is rheumatoid factor, an abnormal antibody that is found with great frequency in rheumatoid arthritis. This year, scientists celebrated the 50th anniversary of the discovery of rheumatoid factor; and we are just uncovering the full significance of this factor. A recent study in Pima Indians has convincingly shown that rheumatoid factor can predict the subsequent development of rheumatoid arthritis. Great interest continues in pursuing the theory of an infectious cause for rheumatoid arthritis, a major crippler among the rheumatic diseases. We are issuing this year a program announcement to the research community to encourage interdisciplinary and other research on the role of infectious agents in causing rheumatoid arthritis. Intramural research on the role of chemicals in the cell walls of bacteria in inducing rheumatoid-like inflammatory arthritis is progressing well.

Lyme disease, initially described as Lyme arthritis, has now become the most prevalent tick-borne disease in the United States, and perhaps in the world. It is now clear that Lyme disease is an infectious disease involving many systems of the body, the joints, skin, heart, and the nervous system. Several challenges face researchers studying Lyme disease. The prevalence of Lyme disease is increasing; it has now been reported in 32 states. Lyme disease has been labeled the "great imitator" as it can mimic many other disorders. Given the wide variety of symptoms, Lyme disease may be difficult to diagnose. The joint lesions of Lyme arthritis are very similar to those of rheumatoid arthritis. These similarities provide a model for in-depth investigations of other diseases that also may be caused by infectious agents. NIAMS has targeted osteoporosis, a serious national health problem, for special research emphasis. We convened last year a very successful scientific workshop on research directions in osteoporosis; it generated 52 specific recommendations for research on osteoporosis. We are supporting three Specialized Centers of Research (SCORs) in osteoporosis, in addition to three each in rheumatoid arthritis and osteoarthritis. We joined with the NIA and the NIDDK in funding three new Programs of Excellence in Osteoporosis. The NIAMS continues as a partner in the multi-institute clinical trial on Postmenopausal Estrogen/Progestin Interventions (PEPI), assessing the effects of estrogen and progestin on cardiovascular diseases and osteoporosis. Among the research advances reported this year, one study clearly confirmed that postmenopausal use of estrogen protects against subsequent hip fracture in women. Accordingly, women should seriously consider taking estrogen during and after the menopause. There was excitement in the research community this year with the first demonstration that bone cells contain receptors for estrogen. The discovery of this relationship between estrogen and bone, at the cellular level provides a new pathway for determing how bone loss occurs in postmenopausal women, as well as how estrogen therapy retards this bone loss. There are also interesting recent nutritional research findings. Dairy products and green vegetables have been generally recognized as excellent natural sources of calcium. Investigators have just found that the absorption of calcium from spinach was 5 percent as opposed to 28 percent absorption from milk. Studies of absorption from additional vegetables and other food sources are under way.

Scientists are continuing to attack lupus on a number of active fronts. As the lead Institute for research on lupus, the NIAMS was pleased to convene and chair the Lupus Erythematosus Coordinating Committee last year and to prepare the almost 300-page report of the Committee to the Congress. The Report outlined the diversity of research on lupus being conducted at the NIH, and the wide range of research opportunities available to scientists for studying lupus. Progress in lupus research this year include characterization of a new antibody, anti-P. This anti-P antibody is found with great specificity in patients with lupus psychosis, but not in other lupus patients or in normal controls. In other investigations, high levels of interferon have been found in most patients with lupus. Whether this is a cause or an effect of the disease remains to be determined. Investigators are seeking to characterize this interferon and to ascertain whether the body's own production of interferon contributes to lupus. Intramural researchers at NIAMS, collaborating with colleagues in the NIDDK, have recently completed long-term studies that indicate that the degree of scarring on kidney tissue may provide important prognostic information in patients with lupus.

Osteoarthritis is the most common form of arthritis and a leading cause of pain and disability. I have reported to you on the major workshop the NIAMS supported on osteoarthritis and the publication of the over 130 recommendations of the experts assembled at the workshop. The proceedings of the workshop provide an agenda for future investigation by identifying and focusing on diverse research approaches to be explored. The Institute, along with the NIA, is currently issuing a Program Announcement, based on the recommendations from the Workshop. Recent research has provided additional insights into risk factors for developing osteoarthritis. Three independent studies have now established that obesity is strongly associated with osteoarthritis of the knee.

Osteogenesis imperfecta is a devastating genetic disease of children causing fragile bones with premature bone fractures, and defects in other organs consisting largely of connective tissues. In a new development, research on osteogenesis imperfecta has moved from the laboratory into clinical practice. A thorough study was performed, tracing the family genealogy and collagen defects of all available members of a family with osteogensis imperfecta. Using important tools of molecular biology, the study confirmed that the gene mutations were located in the same regions as those that had been predicted. Researchers now have the capacity to identify defective genes for osteogenesis imperfecta in both parents and offspring.

Included in the research portfolio of NIAMS is a strong basic research program on muscle biology. Fundamental knowledge is being provided by researchers within that program, both extramurally and intramurally. They are exploiting a promising new model that is providing insights into how muscle contraction is regulated at the molecular level. These scientists are providing us with basic new findings with which to understand muscle tone, muscle metabolism, and the effects of exercise.

The American public is increasingly aware of the many benefits of exercise. Participation in sports and recreational activities is growing. The NIAMS welcomes the opportunity to provide leadership and focus on the benefits, as well as risks, of this growing participation and also to explore fully the characteristics of musculoskeletal fitness. The Institute co-sponsored, with the American Academy of Orthopaedic Surgeons, an important symposium last June on injury and repair of the musculoskeletal soft tissues, an area of great relevance to sports medicine. Scientists have made a new contribution to our understanding of tendon repair and healing. Standard medical practice had been to immobilize injured tendons. Recent research, summarizing a 7-year study, indicates that healing occurs faster and with fewer side effects if injured tendons are mobilized early at increasing levels. The intramural Orthopaedic Research Unit of NIAMS has developed a new model for studying fracture healing that is expected to provide new research strategies for speeding bone repair.

Paget's disease is a chronic disease of the skeleton characterized by abnormally rapid bone turnover. In this disease, excessive bone breakdown and formation result in bone that is dense, though fragile. A recent workshop on Paget's disease, jointly sponsored by the NIAMS, NIDR, and the Paget's Disease Foundation, served to define recent advances and provided guidance for future research on the cause of Paget's disease and new approaches for its clinical management. The NIAMS will issue a program announcement in FY 1988 to alert the research community to the areas identified at the workshop for future investigation.

Low back pain is the leading cause of limitation of activity in young adults 17 to 45 years of age. Moreover, back pain is the second most common ailment in the United States; the first is headache. The NIAMS has planned a workshop on New Perspectives in Low Back Pain Research to be held in May 1988. The workshop will emphasize new research directions for low back pain; it will include both clinical and basic science sessions.

Epidermolysis bullosa (EB) is a group of genetic diseases that involve both the skin and mucous membranes. It is a disabling disease that causes severe blisters, and wounds that resemble severe burns. Considerable progress is being made in our fight against this tragic disease. The registration of EB patients and their families, initiated last year, is up and running at four clinical centers throughout the country. Patient recruitment is ahead of schedule. We intend to launch a clinical trial on EB patients with esophageal strictures. I would like to share with you two significant advances from research on EB this year. The first is a successful new treatment for EB, a skin graft technique, that involves covering blistered parts of the body with cultured sheets of skin grown from small bits of normal skin from the patient. The second is that it is now possible to identify, with great precision, in the skin's basement membrane zone, the specific area of skin that is affected by various forms of EB. Characterization of a new human collagen, Type VII collagen, a major component of the anchoring fibrils that are defective in EB, is continuing. Anchoring fibrils link the outer layer of the skin, the epidermis, to the skin's inner layer, the dermis.

Scientists have reported good news for patients suffering with psoriasis. New therapies, employing the immunosuppressive agent cyclosporin A and derivative forms of vitamin D, have been shown to be effective in many patients in whom standard treatments have failed. That this immunosuppressive agent is effective for psoriasis is re-directing research on psoriasis to immunologic mechanisms.

Investigators continue to make great strides in dermatologic research by applying the advanced tools of molecular biology to study the structure and function of keratins, the proteins that are the main component of the outer layer of skin, hair, and nails. Using cloned DNA, researchers are able to modulate the synthesis of keratin in tissue culture, an important step toward conquering and treating diseases of keratin, such as the ichthyoses. Other studies have helped to clarify the nature and role of lipids, the fatty substances in the skin. This has promising implications for the design of topical agents, both to preserve moisture in the skin, which is lost in some diseases, and to enhance penetration of the skin by drugs. The NIAMS will fund two core centers for skin diseases in FY 1988 to accelerate research on skin and skin diseases. These centers will provide a focus for innovative research and shared resources in investigations on various cutaneous diseases.

New avenues of research are emerging related to AIDS and areas within the mission of the NIAMS. Recent reports suggest that skin eruption may be the first clinical sign of exposure to HIV infection and, thus, may provide an early marker for diagnosing AIDS. Investigators are also seeking to explore a biological connection between certain forms of arthritis or psoriasis and AIDS, based on reports of the co-occurrence of AIDS or HIV positivity with severe Reiter's syndrome, a form of arthritis, and psoriasis. Researchers have also uncovered the possibility that an accelerated onset of AIDS may be associated with HIV-positive individuals treated with certain immunosuppressive drugs, such as methotrexate, widely used for the treatment of rheumatoid arthritis or psoriasis. Our intramural scientists are applying sophisticated techniques developed in their laboratory to construct a structural map of HIV proteins. This may have potential for vaccine development. The NIAMS convened a workshop on Opportunities for AIDS Research in Dermatology and Rheumatology in December 1987. The workshop served to bring together investigators in AIDS as it relates to skin diseases and arthritis, as well as outstanding epidemiologists. The NIAMS is very enthusiastic about the focus this workshop provided in these emerging areas and the valuable suggestions offered for avenues of future research.

The NIAMS was privileged to participate in this extraordinary year of celebration of the Centennial of the NIH. We were so impressed by the strides that have been made in the last 100 years and are confident that research in the next 100 years will achieve progress in ways beyond our imagination. Our goal is to foster such progress in the difficult and debilitating diseases within our Institute's mission. The highlights of advances reported here indicate that we are headed in the right direction. We are grateful to the NIH and to the Congress for the essential and generous support it has offered as the NIAMS develops and grows.

Mr. Chairman, the 1989 budget request for this Institute is $158,224,000. I will be pleased to answer any questions you might have.

# BIOGRAPHY OF DR. LAWRENCE E. SHULMAN

July 25, 1919, Boston, Massachusetts

Education: Harvard University, A.B., 1941; Yale University Graduate School, Ph.D., 1945; Yale University School of Medicine, M.D., 1949.

Professional History: 1949-50, Intern, Medicine, The Johns Hopkins Hospital, Baltimore, Maryland. 1950-51, Ayerst, McKenna and Harrison Fellow in Endocrinology, The Johns Hopkins University School of Medicine. 1951-52, Vernon D. Lynch Fellow in Internal Medicine, The Johns Hopkins University School of Medicine. 1952-53, Assistant Resident, The Johns Hopkins Hospital. 1954-present, Physician, The Johns Hopkins Hospital. 1955-75, Director, Connective Tissue Division, Department of Medicine, The Johns Hopkins University School of Medicine. 1960-66, Physician-in-Charge, Arthritis Clinic, The Johns Hopkins Hospital. 1956-67, Physician-in-Charge, Connective Tissue Clinic, The Johns Hopkins Hospital. 1966-69, Physician-in-Chief, Division of Chronic and Community Medicine, The Baltimore City Hospitals, Baltimore, Maryland. 1970-73, Associate Professor of Medical Care and Hospitals, The Johns Hopkins University School of Hygiene and Public Health. 1964-present, Associate Professor of Medicine, The Johns Hopkins University School of Medicine. 1976-80, Acting Associate Director for Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Metabolism, and Digestive Diseases. 1980-83, Associate Director, Arthritis, Musculoskeletal and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1983-1986, Director, Division of Arthritis, Musculoskeletal, and Skin Diseases, National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases. 1986, Acting Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases. 1987-present, Director, National Institute of Arthritis and Musculoskeletal and Skin Diseases.

Professional Organizations: American Association for the Advancement of Science, American College of Physicians, American Federation for Clinical Research, American Rheumatism Association (President, 1974-75), American Society for Bone and Mineral Research, The Arthritis Foundation, Brazilian Society of Rheumatology, Carla Curzio Neapolitan Society, Lupus Foundation of America, New York Academy of Science, Pan American League Against Rheumatism (President, 1982-86), Society for Clinical Trials, Sydenham Society, Society for Investigative Dermatology.

Honors, Awards: Senior Investigator Award, The Arthritis Foundation, 1957-62. Pemberton Memorial Lecture, 1963. Fellow, American College of Physicians, 1967. Wallace R. Graham Memorial Lecture: Toronto, 1973. The Heberden Medal for Research in the Rheumatic Diseases, Heberden Society, London, 1975. Distinguished Service Award, The Arthritis Foundation, 1979. Honorary Member, Brazilian Society of Rheumatology, 1980. Honorary Member, Chilean Society of Rheumatology, 1981. Knowles Lecture: San Francisco, 1982. Honorary Member, Costa Rican Association of Rheumatology, 1984. Honorary Member, Australian Rheumatism Association, 1985. The Public Health Service Superior Service Award, 1985. National Lupus Hall of Fame, 1986. Elected Master, American Rheumatism Association, 1987. Honorary Member, Swiss Society of Rheumatology, 1987.

## SPONDYLOLITHESIS AND SPONDYLITIS

Senator CHILES. Thank you.

What is the difference between, or how are they familiar or are they different from rheumatoid arthritis—you have mentioned the other, the tick disease, and I understand how it differs, but diseases like some of the other neuralgia and then like spondylolisthesis?

Dr. SHULMAN. Spondylolisthesis. And there is spondylitis, as well.

Senator CHILES. What is the difference between spondylitis and spondylolisthesis?

Dr. SHULMAN. Spondylitis is inflammation of the joints of the spine. Ankylosing spondylitis is the most common type of arthritis in young men; they develop a poker spine.

Spondylolisthesis is a slipping of one vertebral body forward over the other one beneath it. It is a slipping of the bones of the spine, in plain talk. Therefore, the vertebral body needs to be put back in its proper position. Sometimes this dislocation can cause a pinching of the nerves as the bone, one vertebral body, slips over the other one.

One is an inflammatory disorder; the other is a mechanical dislocation.

Senator CHILES. The inflammatory disorder is——

Dr. SHULMAN. Ankylosing spondylitis.

Senator CHILES. Spondylitis

Dr. SHULMAN. Itis as a suffix means inflammation.

Senator CHILES. It is a degenerative disease?

Dr. SHULMAN. Spondylolisthesis is somewhat degenerative, but I think there may be some genetic factors associated with it. Spondylitis is an inflammatory disorder causing destruction of the sacroiliac joints; it then moves up to involve other joints of the spine.

Senator CHILES. What, new treatment for those?

Dr. SHULMAN. The nonsteroidal antiinflammatory agents have been shown to be quite effective in the treatment of ankylosing spondylitis. Indomethecin, for example, has been very effective. Phenylbutazone, before its blood toxicity was fully appreciated, was also very effective in the treatment of ankylosing spondylitis.

People with ankylosing spondylitis function better overall than do people with rheumatoid arthritis, by and large. People with spondylitis are extremely successful. An acquaintenance of Dr. Wyngaarden's and myself developed ankylosing spondylitis when he was in his teens. He has been a remarkably successful surgeon and administrator. Studies have shown that you do not develop as much disability from spondylitis as you do from rheumatoid arthritis.

## OSTEOPOROSIS

Senator CHILES. We have seen a number of stories, recently, about many of the over-the-counter calcium tablets to prevent osteoporosis, that they are ineffective.

What can you do about it?

Dr. SHULMAN. This is something new, Senator Chiles. The data were presented at a recent conference at the NIH, sponsored primarily by the FDA. A professor of pharmacy at the University of Maryland was reporting on a study, which was carried out in the Metropolitan Washington area, as to how many of the calcium preparations break up readily, and how many go into solution. The astounding figure was that of the preparations so tested, about one-half of them failed the disintegration test, and about one-half of the preparations failed to go into solution. I think the FDA will be pursuing this in terms of public education.

Senator CHILES. Well, have you all urged the FDA to look at that?

Dr. SHULMAN. They are looking at it. It was presented at that conference, and that whole office knows about it and will be pursuing that issue.

Senator CHILES. Well, has there not been some problem that estrogen has sometimes caused cancer?

Dr. SHULMAN. The estrogen question is a very complicated one. Estrogen has some good things about it, and some defects. Estrogen in the higher doses that used to be given produced an excess amount of uterine cancer. The dosage has been reduced down to 0.625 milligrams of estrogen. The excessive amount of cancer of the uterus has been reduced but by no means eliminated. That is on the negative side that needs to be addressed.

Estrogen also is very good for the lipids, our blood fats but it may also be very good for the heart because it is good for the lipids. It has been shown to be good for the bones. It has defects in terms of continued bleeding which is a disincentive for many women to take estrogen. There are factors both on the positive side and on the negative side.

Then to compound this further is that the other hormone that participates in the menstrual cycle, which is the progestin, has other effects on the bones, on the lipids, and on cancer, which also have to be factored in. As a result, the National Heart, Lung, and Blood Institute, the National Institute of Child Health and Human Development, the National Institute of Diabetes and Digestive and Kidney Diseases, and our Institute are participating in a study called the PEPI study, which is called the postmenopausal estrogen and progesterone intervention study. This study has seven centers and a coordinating center to look at the positives and the negatives about these hormones and to come up with some practical, good recommendations on the basis of sound data.

### INFECTIOUS DISEASE THEORY OF ARTHRITIS

Senator CHILES. Last year the committee urged that additional attention be focused on the infectious disease theory of arthritis.

What progress has been made in this regard?

Dr. SHULMAN. We are continuing to pursue that and have very active research, searching for not only bacteria, but also for several viruses that are currently under investigation; EB virus and retroviruses in goat models. We have parvovirus, a small virus, that in preliminary data has been found to be associated with rheumatoid arthritis, but the data have not yet been confirmed.

We also have some very interesting data on chemicals, called peptidoglycans, in the cell walls of bacteria that are able to induce arthritis in experimental animals. This is a very hot area both in our extramural program and in our intramural program with Dr. Wilder. It is a very active research field.

We have issued a program announcement to stimulate even further research in this area, and are looking forward to many more applications in this very promising area.

### INTRAMURAL RESEARCH

Senator CHILES. The Arthritis Institute is the newest Institute, with less than 6 percent of the total provided to the Institute for intramural research, compared to about 11 percent on your NIH average. I understand you are interested in seeing the percentage grow.

What areas of intramural research do you hope to expand?

Dr. SHULMAN. The Senate, year before last, in its report language, requested that an evaluation be completed and a report be given to you on the intramural research program 1 year after the new Institute Director had been appointed. We have submitted that report; I will give you the report right now, and you will see that we have received numerous suggestions for further research coming from leaders throughout the country. We have consulted our senior intramural staff for their suggestions, and we convened a high level advisory panel meet last summer on this very subject. They have given us some very specific recommendations for the future development of the intramural program at the Institute, including six new areas of laboratory research and four new disease areas to be pursued in the intramural program.

They are listed for you right there in the report.

### DERMATOLOGY CORE RESEARCH CENTERS

Senator CHILES. With the funding provided last year, the Institute I understand is in the process of creating two new dermatology research centers. When do you expect to make awards for those?

Dr. SHULMAN. In September, sir.

Senator CHILES. Dr. Alexander?

## NATIONAL INSTITUTE OF CHILD HEALTH AND HUMAN DEVELOPMENT

Dr. ALEXANDER. Mr. Chairman, the National Institute of Child Health and Human Development is the focal point at NIH for research on the health of mothers and children and addresses some of the problems of most importance and concern to our society. Foremost among these is infant mortality.

As part of our Institute's low birth weight prevention research initiative, we are supporting behavioral and biomedical research on the initiation of labor, control of fetal growth, maternal cigarette smoking, nutrition, prenatal care, and strategies to discourage teenage pregnancy.

As part of this effort, cooperative clinical trials are being initiated this year in our maternal-fetal medicine network. These trials are assessing the best management for postterm pregnancy, and for premature rupture of the membranes, and the use of aspirin to prevent preeclampsia.

In our network of neonatal intensive care units, clinical trials are underway to evaluate the effectiveness of IV gamma globulin in preventing infections in very low birth weight infants and are planned to assess vitamin E as a way of preventing intracranial hemorrhage.

An emerging contributor to infant and childhood mortality is pediatric AIDS. The Institute's research on pediatric AIDS addresses transmission from mother to child, diagnosis of infection in the newborn infant, effect of the virus on fetal and child development, methods to teach children of various ages about AIDS and how to avoid acquiring it, and in a nationwide clinical trial in about 30 pediatric centers, looking at the effectiveness of IV gamma globulin in slowing the progress of the illness.

NICHD also has a major role in the gene mapping activities of the NIH. We have established the gene probe repository that is a key element in this work, and we are cloning and mapping genes for numerous disorders that cause mental retardation and support and integrate the work of eight different teams that are working on mapping the portion of chromosome 21 that is responsible for Down's syndrome.

A major advance against typhoid fever, a disease primarily of developing countries, came from NICHD in the past year. A new typhoid fever vaccine, developed in our intramural laboratories, passed its field trial in Nepal with flying colors. This vaccine costs less than 10 cents per dose; it has no side effects; it appears to provide long-term immunity with one dose and is at least 80 percent effective. We expect it will be adopted quickly for worldwide use.

Dr. Wyngaarden earlier described for this committee the research of NICHD's intramural scientist, Dr. Michael Zaslov, with magainins. This is a picture of the African clawed frog—I did not bring a frog along—that Dr. Zaslov used to isolate magainini. He made the observation that skin incisions in this frog never became infected in spite of the dirty environment in aquariums and ponds in which these frogs live.

Magainin, the natural protective factor that he isolated from the frog's skin, has extraordinarily broad antibacterial and antimicrobial activity in the test tube. It kills bacteria, viruses, protozoa, fungi, and parasites, including the malaria parasite, without harmful effects on cells.

We are now testing whether that activity will carry over to the intact animal. Since this Institute also does contraceptive research, we have even tried magainin as a spermicide. It works for that, too.

So this holds out the promise that it might have a combined use as a spermicide and an agent that will be effective in combating sexually transmitted diseases.

Senator CHILES. It does all the work of dynamite without the explosives.

Dr. ALEXANDER. It does everything except grow hair, I guess.

PREPARED STATEMENT

The fiscal year 1989 budget request, exclusive of AIDS for our Institute is $397,945,000.

I would be pleased to answer any questions.

[The statement follows:]

# STATEMENT OF DR. DUANE F. ALEXANDER

The National Institute of Child Health and Human Development (NICHD) is the focal point at the National Institutes of Health (NIH) for research pertaining to the health problems of mothers and children, understanding human development and reproduction, and population trends. As such, the NICHD research program targets some of the problems of greatest importance and concern to our society. In maternal and child health, these problems include mental retardation, birth defects, low birth weight, pediatric and maternal AIDS, learning disabilities, Sudden Infant Death Syndrome, and childhood accidents and injuries. In the area of reproductive and population sciences, research is directed toward developing safer and more effective methods of contraception; evaluating the safety and effectiveness of currently used methods; devising strategies to help reduce the number of teenage pregnancies; overcoming infertility; and investigating, at the molecular and genetic level, the mechanisms of human reproductive biology.

Since its establishment in 1962, a primary goal of the NICHD has been to reduce the Nation's infant mortality rate. Currently, the U.S. ranks 16th worldwide in infant mortality with a rate of 10.4 deaths per 1,000 live births, a drop from 25.3 over the past two and a half decades.

The critical factor in further reducing infant mortality is the prevention of low birth weight. Scientists are concentrating on such basic factors as discovering what biochemical signals initiate the start of labor, ascertaining what controls fetal growth, and developing interventions to correct the problems that retard growth in utero. The NICHD recognizes that some portion of low birth weight is attributable to socioeconomic and lifestyle factors. Therefore, as part of its Low Birth Weight Prevention Initiative, the Institute supports behavioral as well as biomedical research on such factors as maternal cigarette smoking, nutrition, prenatal care, strategies to discourage teenage pregnancy, and family planning issues such as spacing of pregnancies. For example, since smoking is the most important known preventable risk factor for low birth weight, Institute scientists are collaborating with the American College of Obstetricians and Gynecologists to develop smoking interventions which may be used in physicians' offices as part of regular prenatal care.

The other major cause of infant mortality is birth defects. In one approach to this problem, scientists are applying new genetic techniques to reach the ultimate goal of preventing birth defects and genetic disorders before they can be expressed; that is, using gene replacement therapy to treat these conditions at the cellular level. At this time, gene replacement therapy in humans is only a hope. But our scientists are achieving some progress towards making that hope a reality. Advances have been made in mapping the human genome and correlating specific genes with specific characteristics or disease states. For example, a team of NICHD-supported scientists has discovered the single gene that apparently determines whether a human embryo will grow into a male or female. This is a major step in understanding a key part of the process by which a fertilized egg develops into a complex, highly specialized adult organism, an understanding that is crucial to designing strategies to prevent birth defects and other disorders that have their origins in the earliest stages of life.

NICHD intramural researchers have identified the genetic defect which determines whether individuals are likely to be susceptible to side effects from certain drugs. The faulty gene causes the body to produce defective versions of a liver enzyme that normally breaks down drugs and environmental chemicals so that they can be excreted. When the enzyme is defective, drugs and chemicals are not properly metabolized and build up high blood concentrations. This research will permit physicians to identify patients likely to suffer adverse effects and to adjust medications accordingly. It also may lead to being able to identify persons at high risk for cancers which are suspected to be caused by chemicals found in the environment or work area.

Genetic engineering is opening other doors as well. This year, scientists succeeded in introducing a human gene into laboratory mice to cause them to secrete in their milk a human protein called tissue plasminogen activator or TPA. The protein, found naturally in human blood, is an anti-clotting agent that shows promise as a treatment for heart attacks. The success with transgenic mice brings scientists one step closer to applying the same technology in animals that produce larger quantities of milk such as cows or goats. We expect that genetic engineering techniques may enable these animals to secrete in their milk large quantities of medically important proteins. These proteins are now produced by bioengineering methods that are expensive and inefficient.

In a major advance, scientists at an NICHD-supported Mental Retardation Research Center followed up on their discovery made last year of the gene defect responsible for Duchenne muscular dystrophy, a severe muscle-wasting disease often associated with mental retardation. That team has now discovered the protein responsible for the specific muscle defect associated with the disorder. Identification of this missing protein may be the key that allows scientists to develop a treatment for this devastating disorder.

On another front, the search is on for the gene or genes responsible for Rett syndrome. Currently, diagnosis of this progressive neurological disorder that affects only girls depends entirely upon observation. The NICHD is supporting research to develop genetic markers and a diagnostic test for this severe disorder and to test and evaluate treatment approaches.

NICHD scientists have made further progress in developing new, more effective and safer vaccines against typhoid fever, pertussis, and Haemophilus influenzae type B. These vaccines are in various stages of human clinical testing, with the typhoid fever vaccine being the closest to market approval. Results from a clinical trial in Nepal show that the new vaccine is more effective, has fewer side effects, and is much less expensive than are currently used typhoid vaccines. Pilot studies of the NICHD pertussis toxoid vaccine in children in Sweden and Massachusetts are confirming our expectations of its increased safety and immunogenicity. These vaccines hold the promise of eliminating illnesses that still extract a huge economic and human toll around the world.

Scientific progress often begins with a fortuitous observation. An NICHD scientist, taking advantage of serendipity combined with his own keen powers of observation, has uncovered a previously unknown way that frogs, and possibly humans, protect themselves against infections. This chemical defense system was discovered when the investigator noted that frogs did not develop infections at the site of surgical incisions even though they lived in bacteria-laden aquariums. Within a year of his observation, using the tools of modern biotechnology, he isolated and determined the structure of the protective substances, synthesized them, cloned the gene that produces them, and determined that the gene is present in most higher animals including man. The search is now on for whether these substances, named magainins for the Hebrew word meaning "shield," are effective in fighting human disease. If they are, a powerful new family of antibiotic drugs may have been discovered.

As new solutions to old problems emerge, new problems arise as well. Over a short period of time, AIDS has become a major public health problem. While there is evidence that, in some populations, the spread of AIDS has slowed, the number of women and children infected by human immunodeficiency virus (HIV) is increasing. The AIDS-related research of the NICHD focuses on the transmission of the AIDS virus from mother to child, the effect of the virus on fetal and child development, methods to prevent the onset of AIDS in HIV-positive children, AIDS treatment, and methods of preventing the sexual transmission of the AIDS virus.

The NICHD has supported the development of a test to monitor the prevalence of HIV antibodies among women of childbearing age by screening newborn infants. This test will now be used in a Nation-wide study conducted by the Centers for Disease Control, in collaboration with the NICHD.

Several NICHD intramural labs are studying HIV infection at its most basic level. One group of investigators has developed a mouse model to help determine what factors turn latent HIV infection into an active disease. Another group is working to understand the biochemical events by which HIV "neutralizes" or inactivates T-cells. This may be an important key to developing effective therapies to treat or prevent AIDS.

As devastating and tragic as pediatric AIDS and other childhood diseases are, preventable injuries kill more U.S. children each year than all childhood diseases combined. Thus, research into mechanisms and antecedents of injury with a goal of preventing childhood injuries is of major importance, and is being pursued in accord with the NICHD Injury Prevention Research Plan developed at the request of Congress. One study seeks to determine the accuracy of parental information regarding hazards in the home. Results from this study represent a first step to describe objectively how parents and children interact with home hazards.

Although not life threatening, learning disabilities frustrate the lives of many American school-aged children. The NICHD has prepared, on behalf of the 13-agency Federal Interagency Committee on Learning Disabilities, the report, Learning Disabilities: A Report to the U.S. Congress. This report proposes a new uniform definition of learning disabilities. The report makes a number of other recommendations, including the establishment of multidisciplinary learning disability research centers, and research to improve the diagnosis, classification, and treatment of learning disabilities. The NICHD is proceeding to implement these and other recommendations in the report.

Behavioral research is also an important component of the Institute's population sciences program. NICHD-supported researchers are trying to determine, for example, why many sexually-active teenagers do not use contraception regularly or at all.

Understanding the reasons behind this reluctance could help researchers develop pregnancy prevention approaches more appealing to these teenagers and help them avoid premature parenthood.

Other NICHD researchers are evaluating the effects of contraceptives that have been widely used in the U.S. One group of researchers, using an ultra-sensitive, highly specific assay for human chorionic gonadotropin developed by NICHD grantees, has demonstrated that the IUD does not appear to operate primarily by causing early loss of an implanted embryo. The researchers determined that fertilization occurs in less than 1 percent of the cycles in women wearing IUDs. Thus, it appears that the IUD effectively interrupts the reproductive process before fertilization.

Several NICHD-supported studies have now shown conclusively that spermicides are not linked with birth defects, quieting fears raised by a controversial report published earlier.

The NICHD supports an active research program to develop new contraceptives that are safe, effective and acceptable to a wide range of people. One of the most promising of these to come from the NICHD Contraceptive Development Initiative is Capronor, a biodegradable implant for women. Capronor, a thin tube that is inserted under the skin, releases small, steady amounts of a contraceptive drug. The device is designed to be absorbed over time and does not need surgical removal. In a preliminary study, no pregnancies occurred among a group of volunteers. Multicenter clinical trials now are being planned.

A second new contraceptive, the cervical cap, is expected soon to receive FDA approval. This device, which works by closely fitting over the cervix and preventing the entry of sperm, has been extensively tested by the NICHD and found to be safe, effective, and convenient to use. This device has eagerly been awaited by consumer groups because unlike currently available barrier methods, it can be left in place for several days.

The Institute's broad research program encompasses both biomedical and behavioral research, from highly sophisticated biotechnological methods, which may one day lead to treating disease at its genetic or molecular level, to developing a vibration device that attaches to a crib to soothe colicky babies. Although the NICHD research program is broad and diverse, its components work in concert to improve the health and well-being of our Nation's children and their families.

Mr. Chairman, the FY 1989 budget request for this Institute is $397,945,000. I will be pleased to answer any questions you have.

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## BIOGRAPHY OF DR. DUANE F. ALEXANDER

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| BIRTH | August 11, 1940, Baltimore, Maryland |
| MARITAL STATUS | Married Marianne Ellis, Washington D.C., June 23, 1963; two children |
| EDUCATION | Pennsylvania State University, University Park, Pennsylvania, B.S. Degree, Pre-Medical, 1962<br>Johns Hopkins University School of Medicine, Baltimore, Maryland, M.D. Degree, 1966 |

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| INTERNSHIP | Intern and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1966-1967 |
| RESIDENCY | Assistant Resident and Fellow, Department of Pediatrics, Harriet Lane Service, Johns Hopkins Hospital, 1967-1968 |
| MILITARY SERVICE | 1968-1970: Surgeon (LCDR), U.S. Public Health Service, and Clinical Associate, Children's Diagnostic and Study Branch, National Institute of Child Health and Human Development (NICHD), National Institutes of Health (NIH), Bethesda, Maryland<br>1971-Present: From Surgeon to Medical Director, U.S. Public Health Service |
| FELLOWSHIP | Fellow in Pediatrics (Developmental Disabilities), John F. Kennedy Institute for Habilitation of the Mentally and Physically Handicapped Child, Johns Hopkins Hospital, 1970-71 |
| LICENSURE | Maryland Board of Medical Examiners |
| CERTIFICATION | Diplomate, American Board of Pediatrics, 1973 |
| POSITIONS HELD | |
| 1971-74 | Assistant to the Scientific Director, NICHD, NIH, Bethesda, Maryland |
| 1974-78 | Medical Officer (Staff), National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, DHEW |
| 1978-82 | Assistant to the Director, NICHD, NIH |
| 1982-86 | Deputy Director, NICHD, NIH |
| 1986-present | Director, NICHD, NIH |

### SMOKING AND PREGNANCY

Senator CHILES. I notice in your full statement you talked about an intervention for smoking with young women that are in their pregnancy.

What would that be? What are you talking about?

Dr. ALEXANDER. This is an intervention study we are designing with the American College of Obstetricians and Gynecologists. It is an office-based intervention that will be used by the physicians with women who come in for their first prenatal visit and are found to be smokers. Three different types of interventions will be tried. Each will try to discourage women from smoking, and, ideally, eliminate smoking during pregnancy. Hopefully these efforts will have a carryover effect after pregnancy as well.

Senator CHILES. What are we talking about?

Dr. ALEXANDER. There are three different interventions that are under assessment. One involves just counseling on the part of the physician at the first prenatal visit and nothing much more in followup after that. Another is a more extensive counseling program involving both the physician, and an office assistant or nurse with followup throughout the pregnancy, and the third is a more intensive intervention with pamphlets and written materials in addition to all of the above. We will be evaluating these various interventions to see how effective they are in reducing the incidence of smoking during pregnancy, and in helping these women to stop smoking on a permanent basis.

These have to be relatively simple interventions that are designed to be used in an obstetrician's practice, and need to take a relatively short time in order to have them adopted by physicians in practice.

Senator CHILES. How do we deal with all of those women who are never in an obstetrician's office but show up in the emergency room and have a low birth weight baby to start with?

Dr. ALEXANDER. It is a little late for them for the smoking intervention program, but we are trying to design programs which will reach these women earlier.

### BETTER BABIES PROJECT

Senator CHILES. How do we try to get our message out?

Dr. ALEXANDER. We are experimenting with a number of other approaches. Here in Washington, DC, through the better babies project that we are partly supporting, we are looking at ways to try and have outreach programs in areas of the community where low birth weight and infant mortality are the highest, to identify women as early in their pregnancy as possible, to encourage them to get into a comprehensive system of prenatal care, and to provide them with ancillary services such as getting into the WIC Program, smoking cessation, drug abuse counseling, and social support services. We are trying to see whether we can get high-risk women into prenatal care earlier and, with this comprehensive care that is provided, lower the incidence of low birth weight and infant mortality.

Senator CHILES. How will you try to identify them?

Dr. ALEXANDER. There is an extensive community outreach effort. This effort includes distributing publicity in the community, and utilizing workers who are in the various high-risk census tracts who have an ear to the ground, if you will, to try to identify these women, make visits to them, and get them into the system of care. This is a different kind of outreach program than has been tried before, and that is really what we are looking at; how effective is the most extensive outreach program you can design in targeting high-risk women and getting them into prenatal care?

Senator CHILES. What kind of history? Do you have any kind of results on that at all yet?

Dr. ALEXANDER. We do not yet, Mr. Chairman.

Senator CHILES. How long is it going to take to really look at the Washington sort of experiment and see whether it can do anything to reduce the low birth weight and, therefore, the infant mortality in the District of Columbia?

Dr. ALEXANDER. This is a 3-year study that is designed, and jointly funded by the NICHD, the Ford Foundation, other foundations, the Bureau of Maternal and Child Health, and the D.C. government. We hope to have some answers within a 3-year period of time.

We have targeted the census tracts that have the highest incidence of low birth weight, about 16 or 17 percent, so if we are going to see results, it should be in those areas.

Senator CHILES. Where are you in that 3 years now?

Dr. ALEXANDER. We are 1 year into the study.

### CONTRACEPTIVE RESEARCH

Senator CHILES. One year.

Tell the committee the contraceptive research you are doing and what new contraceptive devices are expected to be available soon.

Dr. ALEXANDER. We are working with a number of agents that we think have promise for new or improved methods of contraception. One of these is capronor. This is a long-acting, implantable device. It is a little rod about 2 inches long, as thick as a pencil lead. It is designed to be implanted under the woman's skin and to be effective in providing contraception for 1 year to 18 months.

It is totally reabsorbed and does not have to be surgically removed, unlike norplant, which is comparable agent, but which has silastic rods that have to be removed after a period of 4 to 5 years. In the trials that have been undertaken so far, there have been no pregnancies, and capronor has been highly acceptable to the women who are participating in the trials, without a high degree or incidence of side effects.

So we think capronor holds great promise.

Other areas that we are working on include developing a vaccine against pregnancy, a method that holds promise for both male and female contraception. We are looking also at inhibin, a new peptide that has recently been isolated and characterized by NICHD-supported scientists. Inhibin offers the possibility of interfering with FSH, follicle stimulating hormone, without interfering with LH, leuteinizing hormone. Again, this would be effective for both male and females.

We are looking at new technologies for delivering contraceptive drugs through the skin using transdermal skin patches. This is similar to the technology that is used in delivering other drugs across the skin. These contraceptive patches use a combination of levonorgestrel and estradiol, and one patch is effective for up to 7 days. The advantage is that a very low constant dose is delivered instead of a large dose that then gradually diminishes as happens when you take a pill.

We are experimenting with other long acting injectables as well, that are effective for up to 6 months with one injection and do not have some of the adverse side effects found in earlier compounds.

Senator CHILES. Do you see any of these as being anywhere close to marketable or being available?

Dr. ALEXANDER. I think the skin patches probably will be among the first that will be on the market. This is because they are using existing compounds rather than entirely new ones. Skin patches are just a new means of delivery, and they should provide a safer dosage level. The other methods are several years away at least.

I should mention that we are also working to improve spermicides and condoms. This is particularly of interest in relation to the hypothesis that barrier methods may also protect against the transmission of the virus that causes AIDS.

Senator CHILES. Now, explain that to me.

Dr. ALEXANDER. Spermicides that currently exist have antiviral capabilities as well. We are presently involved in testing spermicides that are on the market to assess which ones have the most antiviral capability against the HIV virus. We also are looking at other compounds that might be added to existing spermicides to enhance this antiviral or antibacterial activity.

In addition, we are examining condoms now on the market, to determine if they are indeed effective in containing the HIV virus, and assessing how frequently they might be expected to fail. We have had a recent meeting with industry representatives to discuss whether we might apply some new materials and technology to improving the design and the manufacture of condoms to reduce the failure rate that they have in use.

## PEDIATRIC AIDS

Senator CHILES. Last year the committee provided the Institute with $5 million for additional research in perinatal AIDS.

Tell the committee the disposition of those research moneys and what new findings we can expect in the pediatric AIDS field.

Dr. ALEXANDER. That $5 million was put to good use, Mr. Chairman. It enabled us to markedly expand our efforts in pediatric AIDS. For example, it enabled us to expand our work on determining seroprevalence. We developed with the Massachusetts Health Department a means of screening newborn infants for antibody to the AIDS virus, using the same blood spots that are obtained rountinely on all newborn infants for PKU and congenital hypothyroidism screening. That technology now has been made available to other States in cooperation with the Centers for Disease Control and is being used as part of a national serosurveillance study to assess the incidence of seropositivity among mothers by the newborn infants' serostatus.

We also developed the clinical trial that I mentioned in the opening statement of administering IV gamma globulin to HIV infected infants to try and assess its effectiveness in slowing the progress of the disease.

We have funded a grant in Africa that is looking at the transmission of AIDS and the impact there of the virus on infant and child development. We are also supporting similar studies in the United States.

We also have funded the American Academy of Pediatrics to develop age-appropriate materials for use in pediatricians' offices for physicians to educate children and parents about AIDS. It is hoped that appropriate education will help protect children from exposure to the virus and acquisition of this disease.

Studies being conducted under a request for grant applications that was issued jointly by the NICHD and the National Institute of Mental Health and looking at the capability of children at various ages of learning about AIDS and similar issues. We then plan to apply this knowledge in education programs around the country.

### PHYSICAL FITNESS OF AMERICAN YOUTH

Senator CHILES. The youth of America rank 21st in the world with regard to their overall physical fitness. The last serious push we had was President Kennedy when he created the President's Council on Physical Fitness.

Is the overall level of physical fitness of American youth of concern to you in the Institute?

Dr. ALEXANDER. It is a concern, Mr. Chairman. We are seeing continuing decline in this area.

The President's Council on Physical Fitness and Sports has the lead role in Government in trying to address this issue. It is not an issue that our research has particularly focused on in the past. It is one that I think we may need to give some attention to in the future.

Senator CHILES. All right, thank you.

Dr. Kirschstein.

### NATIONAL INSTITUTE OF GENERAL MEDICAL SCIENCES

Dr. KIRSCHSTEIN. Mr. Chairman, I think what you have been hearing this morning from my colleagues indicates that there has been an enormous explosion in our knowledge and understanding regarding the genetic, cellular, and molecular phenomena that are essential to life and health. Indeed, the dramatic advances that they have been telling you about have emphasized the essentiality of the basic, fundamental biomedical research supported by the National Institute of General Medical Sciences.

You have heard about a gene being identified for muscular dystrophy and about a genetic marker being found for cystic fibrosis. Hardly 1 month now goes by that a new marker for another genetic disease is not found, using techniques which capitalize, in a practical way, on the fundamental research discoveries made by NIGMS grantees.

At the end of fiscal year 1988, with the additional $17.3 million provided to NIGMS by the Congress for the so-called gene mapping project, we will award a number of new grants. This will significantly increase the research and technical developments aimed at constructing a high resolution physical map of the human genome and at expanding the genetic map.

These NIGMS efforts are very important steps in the initiative that NIH is now planning in the expansion of the human genome project.

But, while we have been emphasizing this kind of activity in molecular biology, I think we should not forget the importance of research in chemical concepts. This year, as has happened four times in the past 10 years, a long time grantee of the NIGMS was awarded the Nobel Prize in chemistry. Dr. Donald Cramm of the University of California in Los Angeles, has been studying the structure of so-called enzyme mimics. He plans to engineer molecules which can form stable yet flexible linkages and which can mimic the actions of natural enzymes to catalyze or speed up essential chemical reactions.

Also with specific funds that were provided by the Office of the Director of NIH, we have awarded six project grants for the study of the structural biology of the AIDS virus. Many people believe that learning about the structural biology, the three-dimensional form of the proteins of the AIDS virus will enable pharmacologists and other basic scientists to develop specific antiviral drugs. These six grants have only been in effect for a little bit less than 1 year, and already, small crystals have been identified for several of the AIDS proteins. These crystals are necessary for further structural studies. Two of the six grants are to industrial concerns. We have held meetings to encourage collaboration and cooperation among all the grantees so that the data will be translated as rapidly as possible into practical products.

I know this rapid application of research results in an area in which you are greatly interested.

All of this has occurred in what we are calling the biotechnological revolution, and you, of course, have been markedly interested in this. You heard, Mr. Chairman, when you attended our meeting on biotechnology research and research training in late March; a good deal of the excitement of about what is going on in biotechnology. We want to thank you for the keynote address that you made at that meeting.

You also heard that in order to capitalize on that burgeoning knowledge and the multitude of interacting disciplines that make up biotechnology, we must continue to provide research training for young, eager scientists-to-be. The need for training researchers in biotechnology is considered critical. We have to realize that the path toward significant research advances requires continued attention and care, the continued encouragement of our youth, and the nourishing of fertile minds so that creative scientists will bring forth significant achievements in the future.

Dr. Alexander just told you about a significant advance made by Dr. Michael Zasloff of the intramural program of the National Institute of Child Health and Human Development. Dr. Zasloff is a graduate of the Medical Scientist Training Program, the M.D. Ph.D. program supported by the National Institute of General Medical Sciences. Students in this program are particularly well trained to do research and to bring that research to bear on clinical problems, just as Dr. Zasloff has done. We are very proud of the record of this program and its graduates.

### PREPARED STATEMENT

Mr. Chairman, the fiscal year 1989 budget request for NIGMS is $676,728,000, without the AIDS component.

I will be glad to answer questions.

[The statement follows:]

## STATEMENT OF DR. RUTH L. KIRSCHSTEIN

In the thirteen years that I have appeared before this Committee, there have been enormous advances in our understanding of the genetic, cellular and molecular phenomena that are essential to life and health. The normal processes of cell division, cell differentiation and the metabolism and secretion of essential chemicals are all being elucidated as we strive to prevent or overcome a multitude of human disorders. Dramatic advances emphasize the essentiality of the basic, fundamental biomedical research supported by the National Institute of General Medical Sciences (NIGMS).

With amazing rapidity, findings from the research laboratory now are being translated into important and useful diagnostic and therapeutic tools. Many of these are products being developed with the use of the new biotechnology based on recombinant DNA methods. Among these products are tissue plasminogen activator (TPA), a new treatment for heart attacks, and a host of diagnostic probes for numerous inherited disorders, such as Huntington's disease, cystic fibrosis, and muscular dystrophy. Most recently, NIH-supported scientists, among them NIGMS grantees, have found the genetic marker for another devastating inherited disease, neurofibromatosis, the disease dramatized in "The Elephant Man." The localization of this marker to Chromosome 17 should make possible the development of a diagnostic probe for this disease as well.

Hardly a month now goes by that a "marker" for another genetic disease is not found, using techniques which capitalize on the fundamental research discoveries of NIGMS grantees. This trend, along with other recent developments, highlights the captivating potential of current and proposed studies in genetics and, undoubtedly, led this Committee to state, in its report on the FY 1988 appropriation, that it:

> ". . . is aware that many scientists are now engaged in a concerted effort to "map" or pinpoint the specific location of genes on chromosomes, especially those genes responsible for inherited disorders. . . . Finding these genes will allow researchers to make copies of them for study, to learn what protein each gene makes, to understand ways to treat disorders that arise from defects in the proteins, and perhaps even to replace defective genes. However, mapping genes on the chromosomes of complex organisms

and determining the order or sequence in which chemical units are arranged represent major challenges."

As you know, the NIH has been supporting a large body of research to characterize complex genomes for many years. The development of genetic maps of a number of complex organisms, maps which link markers to certain inherited traits, has progressed with great rapidity. The expansion of mapping research will rely on the work of a number of scientists already supported by NIGMS. One, Dr. Charles Cantor of Columbia University, along with his colleagues, has developed a technique called "pulsed-field gel electrophoresis" which simplifies the manipulation of, and allows the separation of, long stretches of DNA. Most recently, in refining this technique, Dr. Cantor has constructed a map of the DNA of that most studied of organisms, the bacterium, E. coli. This DNA has been cut into 22 contiguous pieces of varying size, making a so-called physical map of the genome of this bacterium. Its construction serves as a model for preparing physical maps of larger, more complex genomes.

Another NIGMS grantee, Dr. Maynard Olson, of Washington University in St. Louis, has developed a method for cloning larger pieces of DNA than previously had been possible. This method uses the genetic material of the common yeast as a cloning vector, into which DNA fragments of other organisms can be inserted. The ten-fold increase in the size of the DNA segments that can be cloned in this manner will greatly facilitate the construction of physical maps of a number of complex organisms. This, in turn, will hasten the completion of genetic maps by better pinpointing specific genes to precise locations on particular chromosomes.

Before the end of FY 1988, with the additional funds provided to NIGMS for the gene mapping project, new grants awarded in this area will significantly increase the research aimed at constructing a high resolution physical map of the human genome, expanding the human genetic map and delineating genetic and physical maps of other complex genomes such as those of the mouse, the fruit fly and yeast. Such mapping projects should have a considerable impact on our understanding of many devastating inherited diseases.

To facilitate and rapidly utilize the genetic information which our grantees are producing--again with the encouragement of this Committee--NIGMS recently renegotiated and awarded an expanded GenBank contract. The nucleic acid sequence data which are accumulating at an ever increasing rate will, thus, be more readily and efficiently available to many biomedical research scientists—not just geneticists but, also, biochemists, cell biologists, pharmacologists, chemists, physicians, and many others, for whom the information is critical to on-going scientific programs.

The importance of understanding fundamental chemical concepts, as well as those of biology, must be underscored. NIGMS supports the chemical sciences very substantially and has been responsible for many of the important advances in chemistry as they relate to the biomedical sciences. This year, as has occurred four other times in the past 10 years, a long-time grantee of NIGMS was awarded the Nobel Prize in chemistry. Dr. Donald Cram of the University of California in Los Angeles has been studying the structure of certain chemicals in order to design simple molecules which mimic naturally occurring enzymes but which have the advantage of much greater stability. These "enzyme mimics" can form stable, yet flexible linkages, tailor-made to speed up essential chemical reactions of importance to the maintenance of health.

In addition to understanding chemistry, learning the physical three-dimensional structure of the essential molecules of life, particularly proteins and nucleic acids, is critical to developing an understanding of their functions. It is for this reason, and in accord with a recent statement by a member of Congress that the "best defense against AIDS . . . is the expansion of our knowledge about basic . . . biology," that NIGMS, with specific funds provided for AIDS research, has awarded a group of six large grants for studies of the structures of the important proteins of the AIDS virus. The goal of these research projects is to design drugs based on the high resolution structures of the viral proteins as determined by X-ray crystallography. It is expected that such specifically designed chemicals will inhibit the viral infection, thus acting as antiviral agents, or even as preventatives of infection. Although these grants have been in effect for less than one year, I am pleased to tell you that good progress is being made. Small crystals of some essential AIDS virus proteins have been produced, and the groups are coordinating their efforts and are communicating among themselves as well as with industrial contacts. Indeed, two of the awards were made to industrial concerns which can, as appropriate, rapidly translate the research findings into products of potential clinical importance.

It is increasingly clear that a number of technologies, such as the so-called biotechnology (recombinant DNA techniques) and X-ray crystallography, have unified biology and chemistry so that a further understanding of many of the mysteries of life processes will be possible. One of these mysteries, clearly related to human health, is how the differential development of neighboring cells and tissues occurs. Cell biologists such as Dr. Marc Kirschner, at the University of California in San Francisco, have shown that particular but variable growth and differentiation factors are responsible for the development of specific tissues in the embryo. It turns out that these factors are produced under the control of a specific genetic process. Genes are turned on and off at different developmental stages and their signals are transmitted by specific messenger RNAs. Moreover, these growth factors are involved, not only in embryonic development, but also in the normal control of growth and differentiation and in the renewal of the tissues and organs of adult organisms.

Also using new methodologies, a grantee of the Pharmacological Sciences Program has been studying certain drugs that suppress the body's immune system. These drugs are used to prevent the rejection of transplanted organs.
Dr. Richard Weinshilboum of the Mayo Clinic has discovered that an enzyme which breaks down these drugs is under genetic control. He has shown that about 10% of the population have an abnormally low level of this enzyme, based on their genetic makeup. Furthermore, he has found a significant correlation between low levels of this enzyme and the toxic reactions which occur in certain patients receiving these drugs. In addition, he has devised a blood test which may serve as a screening procedure to predict whether adverse reactions will occur when such drugs are administered and thus permit physicians to plan therapeutic regimes more rationally.

All of these exciting and rapidly expanding developments, this so-called revolution in biology, have been possible because of the prepared minds of creative biomedical research scientists in the universities and medical schools of the United States. To capitalize on this burgeoning knowledge and the multitude of interacting disciplines that make up the new biology and biotechnology, we must continue to provide research training to young, eager scientists-to-be. The multidisciplinary predoctoral research training programs and postdoctoral fellowships supported by NIGMS perform this critical role in melding training for research in the biological, chemical and physical sciences. Again, with support from the Congress, a new predoctoral research training program in molecular biophysics has been initiated, designed to focus on the application of physics, mathematics and chemistry to the problems of biological structure at the molecular level. This new research training program is complementary to the research grants awarded for studies of the structural biology of the AIDS virus and, by following the lead of those exciting scientific endeavors, will assure needed research manpower to continue and, indeed, to enhance, our basic knowledge of human biology.

As you well know, there are two very special NIGMS research training programs. One, the Medical Scientist Training Program (MSTP) is for highly motivated and particularly creative young students who want an integrated combined biomedical and clinical research training program. Increasingly, these students are the authors of scientific papers in the best scientific journals. In addition, this year, one MSTP graduate was given special awards from both the National Academy of Sciences and the Passano Foundation, while another student was awarded a prestigious Rhodes scholarship.

The other special training program, the Minority Access to Research Careers (MARC) Program, is designed to increase the number of well-trained minority students who enter research careers. Of great significance is the fact that more and more of the graduates of the MARC Honors Undergraduate Programs are being admitted to the NIGMS-supported Medical Scientist Training Programs. Among them are students at Stanford University, and the University of Pennsylvania and Mount Sinai Medical Schools.

Mr. Chairman, each year that I have come before you, I have said that much remains to be learned. While progress in basic research thus far has been impressive, it is really only a tantalizing beginning toward understanding the vast and awesome unknown of fundamental normal biological processes, and of what goes awry in many human disorders. Once again, I can assure you of the high quality, and importance to scientific progress, of the NIGMS-supported research and research training programs. Without such programs, our understanding of biological processes would be far less and the outlook for improved health far dimmer.

The path toward significant advances requires, however, continued attention and care, continued encouragement of our youth and the nourishing of fertile minds so that creative scientists will bring forth significant achievements. It also requires that we all realize that thinking about and undertaking biomedical research problems is an intensive, difficult task needing patience and fortitude. To provide such, in order to fulfill our expectations of continued progress, is what NIGMS is all about.

Mr. Chairman, the FY 1989 budget request for NIGMS is $676,728,000. I will be pleased to expand on any points and answer questions.

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## BIOGRAPHY OF DR. RUTH L. KIRSCHSTEIN

October 12, 1926. Brooklyn, New York

Education: A.B., magna cum laude, Long Island University, 1947. M.D., Tulane University School of Medicine, 1951.

Professional History: 1951-52, Internship, Medicine and Surgery, Kings County Hospital, Brooklyn, N.Y. 1952, Assistant Resident, Pathology, Veterans Administration Hospital, Chamblee, Ga. 1952-54, Resident, Pathology, Providence Hospital, Detroit, Mich. 1954-55, Trainee of National Heart Institute and Instructor in Pathology, Tulane University School of Medicine. 1956-57, Medical Officer, Resident in Pathology, Clinical Pathology, Clinical Center, NIH. 1957, Medical Specialty Board Certification, Pathology (anatomic and clinical pathology). 1957-60, Medical Officer, Pathologist, Laboratory of Viral Products, DBS, NIH. 1960-62, Chief, Section of Pathology, Laboratory of Viral Immunology, DBS, NIH. 1962-64, Assistant Chief, Laboratory of Viral Immunology and Chief, Section of Pathology, DBS, NIH. 1964-65, Acting Chief, Laboratory of Pathology, DBS, NIH. 1965-72, Chief, Laboratory of Pathology, DBS, NIH. 1971-72, Assistant Director, Division of Biologics Standards, NIH. 1972-73, Acting Deputy Director, Bureau of Biologics, FDA. 1973-74, Deputy Associate Commissioner for Science, FDA. 1974-present, Director, National Institute of General Medical Sciences, NIH.

Professional Organizations: American Association of Immunologists; American Association of Pathologists; American Society for Microbiology; Institute of Medicine, National Academy of Sciences.

Committee Memberships: Invited member of World Health Organization Expert Group on International Requirements for Biological Substances; Geneva, Switzerland, 1965 and 1971. Invited consultant to World Health Organization concerning problems related to the use of Poliovirus Vaccine, Live, Oral; Geneva, Switzerland, 1967. Member, Primate Research Centers Advisory Committee, Division of Research Resources, NIH, 1971-1975. Member, National Commission on Diabetes, 1975. Member, National Commission on Arthritis and Related Musculoskeletal Diseases, 1975. Chairperson, NIH Grants Peer Review Study Team, 1975-1976. Chairperson, PHS Genetics Coordinating Committee, 1976-1979. Member, Fogarty International Center Scholars-in-Residence Advisory Committee, 1977-1982. Member, NIH Coordinating Committee on Manpower, 1978-1983. Chairperson, PHS Task Force on Women's Health Issues, 1983-1984. Chairperson, PHS Coordinating Committee on Women's Health Issues, 1984-present. Member, NIH Advisory Committee for the IOM Study of the Organizational Structure of the NIH, 1983-1984. Member, HHS Executive Development Board, 1985-present.

**Honors, Awards:** Elected to Institute of Medicine, National Academy of Sciences, 1982. Doctor of Science, Honoris Causa, The Mount Sinai School of Medicine, 1984. Honorary Doctor of Laws, Atlanta University, 1985. DHEW Superior Service Award, 1971. PHS Superior Service Award, 1978. Presidential Meritorious Executive Rank Award, 1980. PHS Equal Opportunity Achievement Award, 1983. PHS Special Recognition Award--group award to PHS Task Force on Women's Health Issues (Dr. Kirschstein, Chairperson), 1985. Distinguished Executive Service Award of the Senior Executive Association, 1985. Presidential Distinguished Executive Rank Award, 1985.

## NEED FOR RESEARCH PERSONNEL FOR BIOTECHNOLOGY

Senator CHILES. Doctor, with regard to the panel that we had meeting out there at which we were looking for bottlenecks in regard to the development of biotechnology products and therapies, you know, of course, one was a shortage of trained personnel. Were any conclusions reached with regard to the adequacy of the numbers and kinds of scientific personnel both currently available and now being trained?

Dr. KIRSCHSTEIN. Yes; there were some conclusions reached, Mr. Chairman.

One of the issues raised was that the scientists needed by the biotechnology industry are now being drawn from a very limited pool. It is clear from what we heard at that meeting, and from other studies, that the biotechnology industry is going to have to increase its personnel in order to keep up with the advances that are occurring so rapidly. The Industrial Biotechnology Association recently estimated that an increase of 23 percent in scientific personnel will be needed by biotechnology firms by mid-1988, and 44 percent by 1989. We will need individuals trained in biochemical engineering, structural biology, protein engineering, and chemistry, but also the industry will need individuals trained in the more classical disciplines for which NIH has provided research training support for a long time. These include microbiology, microbial physiology, microbial ecology, enzymology, pharmacology, toxicology, virology, and chemistry.

There is indeed a great need for additional scientific personnel. NIH provides about 76 percent of all the Federal support for predoctoral research training of biomedical scientists. Without continued training of large numbers of people, not only will our academic institutions suffer because a critical time is coming when a large number of faculty members will be retiring, but industry will suffer as well.

The meeting participants estimated that, overall, we should move toward a steady state of about 1,000 to 1,500 new trainees a year. They recommended that to reach this number, we start with a program of about 250 trainees in the biotechnological areas in the very near future.

Senator CHILES. Well, I notice some 43 of the biotech firms report being short of trained researchers, and that the shortage nationwide is estimated to be about 2,000.

How many biotech researchers could we effectively start in a training program in 1989?

Dr. KIRSCHSTEIN. We think about 250, of which about 100 would be trained in the more classical areas that we have been discussing, and about 150 would be trained in areas more directly related to biotechnology. The latter would be a new area of training for NIH, because what we are talking about now is taking individuals with, perhaps, a biological background who would train in engineering, for example, protein engineering and chemical engineering. People trained in engineering would be taught to do research in molecular biology.

Some of the candidates for such training are really quite far advanced in their careers, so that we are thinking about two special portions of this training program: a senior fellowship program and an internship program, in which persons from academic research settings would spend internships in biotechnology firms, and individuals in biotechnology firms would spend time in academia. This will accomplish several things. It will increase the number of well-trained individuals who can move into industry, and will also strengthen the ties that already exist between academia and the biotechnology industry.

### INDUSTRY SUPPORT FOR BIOTECHNOLOGY TRAINING

Senator CHILES. Recognizing that there is tremendous advantage for these private firms to have these personnel, how do we get into some kind of a consortium with them in which they match part of the money and we try to leverage our funds that way?

Dr. KIRSCHSTEIN. The meeting participants thought about that, Mr. Chairman.

First of all, there are presently over 30 biotechnology centers that are supported by university-State consortia. Two of them are in the State of Florida, with one for example, associated with the University of Florida. There are such organizations all across the country. These groups could be the basis for such training programs.

Furthermore, as I said, many of the individuals to whom one wants to aim such training are fairly far advanced in their careers. The stipends that NIH, at the present time, can pay such individuals are limited by what we feel is appropriate for the more usual type of trainee. It should be possible to develop matching programs in which compensation to supplement stipends for such senior personnel could come from the industry. Such a matching program could ensure a training program having a proper balance between young people just entering their graduate work, more advanced individuals at the postdoctoral level and senior fellows learning new disciplines.

### PLANS FOR BIOTECHNOLOGY TRAINING PROGRAM

Senator CHILES. If we were talking about beginning with 250, and you are saying we need somewhere, 1,000, 1,500 that would be trained every year, how long would it take us to ramp up to that?

Dr. KIRSCHSTEIN. About 5 or 6 years.

Senator CHILES. Do you have a definite plan, or can you put together one?

Dr. KIRSCHSTEIN. We can put together a plan. In fact, the group did put together a plan which was included as a series of principles in the report of the meeting on biotechnology research and research training. It will soon be coming to you. You will recall that this committee had asked for a specific report which we submitted several months ago. We wrote up the results of the recent meeting and presented a series of principles on how such a training program in biotechnology should be developed. These are outlined in a report which is on its way, through clearance, to you.

Senator CHILES. Well, I have not seen that report, but I would hope that or another report that you would give us would show us exactly what you think the ramp could be.

Dr. KIRSCHSTEIN. Yes, sir; we have such ideas.

[The information follows:]

# A Plan for Biotechnology Research Training

## I. Background

The preeminence of the United States in the competitive arena of biotechnology is primarily due to the substantial investments in basic biomedical research made over the past several decades by NIH and other Federal agencies through programs authorized by the Congress. NIH provided approximately $2.4 billion for biotechnology-related research in Fiscal Year 1987. Other Federal agencies provided an estimated $400 million and the biotechnology industry, itself, spent about $1.9 billion for research and development in biotechnology. However, the competitive advantage that the United States has enjoyed is now being aggressively challenged as a result of recent investments in biotechnological research made by both the governmental and industrial sectors of Japan and by a number of western European countries.

While the support provided by the Federal sector for biotechnology research, channeled through a variety of mechanisms, has been of crucial importance for the progress achieved and must be sustained, several substantial research needs exist in this area. These needs are in a number of research areas where essential steps in the pathway from basic discoveries to commercial products are currently rate-limiting in regard to the realization of increased opportunities otherwise available in the biotechnology arena. Moreover, the enormous growth of the biotechnology industry has resulted in critical shortages of experts in biochemical engineering, macromolecular structure, protein engineering, immunogenetics, chemistry, and other areas that coincide with the major biotechnology research needs described above. There is also an increasing demand for bioscientists trained in more classical areas such as microbial physiology, microbial ecology, enzymology, pharmacology/toxicology, physiology, virology, biological chemistry, and cell biology, areas needed to assure that products developed commercially are safe, effective and appropriately used as they are brought to market.

Based on recent surveys conducted by the Industrial Biotechnology Association and a soon-to-be released report by the Office of Technology Assessment, there is a current need for about 1,000-1,500 biotechnological trainees in several programmatic areas. The results of an even more recent survey by the Industrial Biotechnology Association indicate that the approximately 40,000 persons currently employed in commercial biotechnology firms need to increase by 23% by mid-1988, and by 44% by June 1989.

The scientists needed for the expanding biotechnology industry are currently being drawn from a very limited and shrinking pool of appropriately trained individuals. This situation undoubtedly will result in shortages in Federal laboratories and an inadequate supply of academic scientists needed for regular faculty replacements. A consideration of the needs of the industrial sector in combination with those of the academic sector, which especially requires replacements for the large cohort of faculty members expected to retire over the next decade, clearly reveals the critical importance of enhancing biotechnology research training programs. Such programs must be adequate to accommodate the increasing personnel needs of the academic, industrial and governmental sectors, which are estimated at 1,000-1,500 trainees over the next five to six years.

## II. Biotechnology Research Training Program

Based on the aforementioned, a university-based biotechnology research training program is proposed, the intention of which is training that focuses on the applications of engineering, physics, chemistry, mathematics, and biology to interdisciplinary biomedical research training. Such biotechnology research training programs would be governed by the following considerations:

1. Biotechnology research training should be an interdisciplinary enterprise targeted toward the production of a new breed of scientists. However, such interdisciplinary training must follow fundamentally sound undergraduate preparation in biology, computer science, chemical engineering, applied mathematics, chemistry, and physics.

2. Biotechnology training programs should have sufficient flexibility to accommodate a variety of candidates, with backgrounds in, for example, chemical engineering, biology, applied mathematics, chemistry, computer science, and physics, and must be interdisciplinary in nature.

3. Biotechnology research training should emphasize state-of-the-art hands-on laboratory courses based on common methodologies (e.g., bioprocess engineering, plant and animal cell culture technologies, biocomputing, macromolecular structure analyses, and hybridoma technology).

4. To ensure formal mechanisms for multidepartmental organization and truly inter- (or cross-) disciplinary training, and to make provision for academic and industrial collaborations in research training, these training programs should be established at institutions with viable biotechnology research programs (centers, institutes, and consortia). A proper balance of participants from both the industrial and academic sectors in such research training should be maintained. Also, provisions should be made for trainees to participate in internships in biotechnology industries. Short-term courses and workshops on biotechnology should be integral components of each training program. Such biotechnology training programs would support:

    a. predoctoral training in the classical biomedical sciences (indicated above) that serve to undergird biotechnology research;

    b. predoctoral biotechnology training in interdisciplinary research; and

    c. postdoctoral training via regular postdoctoral fellowship programs, postdoctoral associateships in industry, and senior postdoctorals for persons who "field-switch" (e.g., a postdoctoral program for scientists in a given field to acquire training more directly related to biotechnology).

5. To make provision for biotechnological education outreach programs, the biotechnology research programs should provide research internships for undergraduate students and conduct short courses/research training modules/exercises for both high-school science teachers and students.

6. The Federal resources committed to the support of such state or university-sponsored biotechnology research training programs should be further augmented by explicit cost-sharing mechanisms, employing the university or state's resources, as well as those of industries collaborating with these biotechnology research and research training organizations.

## III. Summary of Identified Needs

1. Biotechnology research training programs represent a major current National need, and should be targeted toward the goal of increasing the National pool of trainees/fellows by about 1,500, adding training candidates at the rate of about 250 per year.

2. Awards for biotechnology research training should be provided for five years, with competitive stipend levels.

3. The panel's budget recommendation for the achievement of a steady state of approximately 1,500 trainees per year, by the end of a 5-year period, is shown on the attached table.

## IV. Conclusions

NIH, along with other Federal agencies supporting basic and biotechnology-related research, must give increased emphasis to existing biotechnological research needs and attendant research training programs. The provision of resources to initiate the recommended new biotechnology training program would ensure the existence of a cadre of scientists well-trained in modern biological techniques. This would represent a major step toward a National strategy for taking advantage of the burgeoning opportunities currently available in biotechnology, and to retain the preeminence of the United States in this field.

National Institute of General Medical Sciences

Biotechnology Research Training Proposal

| | 1st Year | | 2nd Year | | 3rd Year | | 4th Year | | 5th Year | |
|---|---|---|---|---|---|---|---|---|---|---|
| | FTTP | Amount | FTTP | Amount | FTTP | Amount | FTTP | Amount | FTTP | Amount |
| Special Senior Fellowships.... | 15 | $600 | 30 | $1,200 | 45 | $1,800 | 60 | $2,400 | 60 | $2,400 |
| Individual Postdoctoral Fellowships................. | 60 | 1,320 | 120 | 2,340 | 180 | 3,960 | 300 | 6,600 | 360 | 7,920 |
| Institutional Predoctoral Fellowships..... | 175 | 2,905 | 350 | 5,910 | 525 | 8,715 | 890 | 15,409 | 1,080 | 19,502 |
| TOTAL.......... ......... | 250 | 4,825 | 500 | 9,650 | 750 | 14,475 | 1,250 | 24,409 | 1,500 | 29,822 |

Senator CHILES. And how we could expect the private sector to match into that.

Dr. KIRSCHSTEIN. Yes.

Senator CHILES. Coordinate with that.

Dr. KIRSCHSTEIN. We have the general outline of that. I have already told you about it.

Senator CHILES. Are you taking into consideration, or would this take into consideration the problem that we are seeing in which, again, many of our teachers are being recruited by the private sector because the funding is so much greater out there, and the shortages, and we are all pulling from the same pool.

Dr. KIRSCHSTEIN. Yes; we are taking that into consideration. That is part of what I was talking about when I said we had to have replacement personnel in academia. Part of the need for scientific personnel is due to the fact that the faculty of academic institutions is aging and there will be a large number of retirements soon. Part of the need results from the losses that universities are suffering to industry, losses that NIH also has recently experienced in its intramural program.

### INTEREST IN RESEARCH CAREERS IN SCIENCE

Senator CHILES. What kind of, aside from the monetary considerations, the costs, what kind of receptivity is there out there on the part of young people to move into this area? Is it high now or is it something that we have got to motivate further?

And put that on a scale in regard to the other careers that are out there available to them, and monetary or other rewards that are out there, in other words.

Dr. KIRSCHSTEIN. There are two parts to that problem. Up until quite recently, I think we all felt that college students found that biomedical research careers were not as attractive, in the past few years, as they had been in the more distant past. Young college students seemed more interested in going into business administration. The master's of business administration was the degree that most young people wanted to get. Perhaps some of the things that have been happening on Wall Street have changed that to some extent.

Now, however, biomedical research looks very exciting. One of the most encouraging things that happened at the meeting on March 28 was that the people who have been involved in training new researchers in biotechnology, particularly Dr. Daniel Wang from the Massachusetts Institute of Technology, told us that engineering graduates are excited about moving into biotechnology. Whereas several years ago Dr. Wang could not find any engineers who wanted to be trained in molecular biology, he has large numbers who do now.

However, I think there is another problem, and it is related to our educational system generally. There has been much discussion recently regarding the fact that our young children, both in elementary school and junior and senior and high school, must become interested in science at a very early age. Decisions regarding careers in science have to be made as young people enter college or certainly very early in their college careers. To interest young people in science, NIGMS has put together some material that is useful for them. We have a series of booklets about molecular biology and genetics that have been published out and written with high school students in mind. These are being distributed to high school science teachers. We hope that we can increase the interest in this field.

There is a real educational job that we, the scientists, have to perform because we need to improve the teaching of science in the public and private schools throughout the country.

### NIH TEACHING SEMINARS AND SUMMER LAB EXPERIENCES

Senator CHILES. Well, I am delighted to hear you are working on this and that you have these pamphlets.

In addition to the pamphlets, which we never know how they get distributed or whether they ever get to the right place, are there anything like teaching seminars or things in which we know there is going to be some kind of a better hands on approach and that you are going to bring in the right people, and you are going to try to stimulate them and tell them what materials can be available?

Dr. KIRSCHSTEIN. There are indeed. Some of us at NIH are involved in special seminar series for teaching high school teachers about genetics and molecular biology.

Summer courses and courses on Saturdays are being sponsored by a number of scientists at NIH, who, on their own, have decided how critical this is.

In addition, the summer high school programs in which we bring young high school and college students into NIH's own laboratories and into the laboratories of scientists in universities throughout the country, are very important in this regard.

Senator CHILES. Are those programs going on, the summer high school programs?

Dr. KIRSCHSTEIN. Some of those programs are going on. The Division of Research Resources has a specific program for minority high school education. In addition, the honors undergraduates component of the Minority Access to Research Careers Program of NIGMS, has been doing a great deal in this regard including providing a summer or semester research laboratory experience. The numbers of minority students that are interested in majoring in science have been increasing rather remarkably.

Senator CHILES. It seems that way, if we could come up with ways to motivate this, for example, in our research centers, if one of our requirements there would be that we would expect them to develop or we help them develop some kind of programs, both for the summer but also outreach and bringing in the science teachers and all, because we are going to have these centers across the country.

Dr. KIRSCHSTEIN. That is right, and many research and biotechnology centers are conducting such programs.

NIH itself gives a program each year called medicine for the layman. I gave the lecture on genetics some time ago, and we had a number of high school students there, as well as high school teachers. And we must do more of this. I agree.

Senator CHILES. Thank you.

Dr. Rall.

## NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

Dr. RALL. Thank you, Mr. Chairman.

The mission of the National Institute of Environmental Health Sciences is to explore the effects of environmental agents on human health. Our research serves to inform physicians, the general public, legislators, and regulatory agencies of the existence of hazardous environmental agents so they may assess the risk of exposure and make sound judgments about how to protect public health. We provide information; we do not regulate.

### LEAD

As I indicated last year, recent NIEHS and NICHD supported research has shown that lead, a very commonly used compound for many years, is much more toxic than we had realized. These toxic effects were hard to detect because they resulted from long-term exposure and took years to develop. The recent research at the University of Cincinnati and Harvard shows that children suffer profound harm from much lower exposures than had been thought to be significant. The Harvard research showed that low levels of lead in pregnant women can affect the neurobehavioral development of the children. The Cincinnati studies indicated that at 10 micrograms per deciliter of blood, the toxic effects begin. The current recommendation is that children be referred for pediatric evaluation if their blood lead level is 25 micrograms per deciliter of blood.

In the entire population, the average lead level is close to 10 micrograms per deciliter of blood in the average adult. Nine percent are above 25 micrograms per deciliter, and in blacks, 25 percent are above 25 micrograms.

Senator CHILES. Why is it so much higher with the blacks?

Dr. RALL. Probably because one of the major sources of lead is the housing in the inner cities. The lead-based paint has still not been removed. Other sources of lead are brought in from the outside such as, from the dust brought on by exhaust from automobiles. Still, lead-based paint is the major source of lead poisoning. This is a very serious problem. We are working with the other NIH Institutes——

Senator CHILES. Well, is there lead-based paint now being used, or this is old paint that is still on the walls.

Dr. RALL. It is the old lead-based paint that has been on the walls for many years.

Senator CHILES. And they have just painted over it or something, and so we have not removed it.

Dr. RALL. It is very hard to remove safely because when you remove it you create great clouds of lead dust, and in many ways it can be more dangerous to remove it than to leave it. HUD is finally beginning to be interested in this. It is a problem we are going to have to face in the future.

### ONCOGENES

Let me briefly mention one or two other areas of research. We have continued our studies with oncogenes, those little bits of protein that seem to turn on cancer cells. We are interested in how we can relate oncogenes in chemically induced tumors in laboratory animals to oncogenes in people. We think this will provide a much better basis for extrapolation of laboratory animal work to man.

### SIX-CITY SURVEY

Finally, our six-city survey which looked at pulmonary development and malfunction in children and adults in three cities across the country which were pristine with respect to their air and three which were quite dirty, is winding up to a close. The results of the study support in general the current standards for the criteria air pollutants but suggest, however, that at the high levels, under the standards, there can be some damage to pulmonary function in persons with preexisting lung disease.

I think this study will provide the basis for the next Clean Air Act standards for the so-called criteria air pollutants.

This elegant epidemiological effort is being turned now into a study on the effects of acid rain, acid precipitation in children and adults. Preliminary studies suggest that, in fact, there are serious pulmonary effects from acid rain episodes.

### PREPARED STATEMENT

The hour is late, Mr. Chairman. Our budget request is for $219 million.

I would be pleased to answer any questions you have.

[The statement follows:]

## STATEMENT OF DR. DAVID P. RALL

The mission of the National Institute of Environmental Health Sciences (NIEHS) is to study the effects of environmental agents on human health. The knowledge gained from NIEHS' work is used in efforts to protect human health from environmental hazards.

NIEHS studies deal with health effects of air pollution, water pollution, ground water contamination, toxic chemical dumps and toxic chemicals in general. The effects of these chemicals and the diseases they cause vary from cancers to kidney disease, pulmonary damage, bronchitis and emphysema, mental retardation, developmental disability, genetic damage, etc. NIEHS research serves to alert physicians, the general public, legislators and regulatory agencies to the existence of hazardous environmental agents so that they may assess the risks of exposures and make sound judgments about how to protect public health and safety.

Today I would like to begin by telling you about recent NIEHS-supported studies on lead, a common environmental element whose dangers we have all heard much about over the years.

Our use of man-made and natural chemicals has yielded enormous economic and societal benefit and has vastly improved human welfare. At the same time, it must be recognized that some chemicals may cause problems. With lead and a number of other chemicals, scientific and medical concern focuses on low-level, long-term human exposure. This uncertainty is heightened because, although we know that exposures are widespread, typically little data exist on actual levels of exposure in homes, work places, schools, or the general environment.

NIEHS-supported research has shown how lead, a compound widely used for millennia, is significantly more toxic than had been appreciated.
Lead has long been recognized as highly toxic in both occupational and environmental settings. For example, there were reports of serious illnesses among workers who produce lead additives for gasoline in the 1920s.
In the 1940s and 1950s when white paint contained 70 percent lead by weight,

children who ingested small amounts of white paint chips often died and those who survived suffered seizures and learning disabilities.

By 1977, the Consumer Product Safety Commission had limited the amount of lead allowed in paint to 0.06 percent and the Environmental Protection Agency now has a target of 0.1 gram per gallon of lead in gasoline, the most recent target set by EPA in a phase-down begun in 1973. By comparison, the concentration permitted in 1981 was 1.1 grams of lead per gallon. The principal reason for this regulatory action was the fact that lead damaged the catalytic converters designed to reduce automobile exhaust emissions containing other non-lead pollutants. But another serious consideration was the scientific evidence developed by environmental health scientists in the 1970s linking elevated levels of lead in elementary school children's blood with hyperactivity and learning disabilities.

Current regulations have been quite successful in limiting the amount of lead added to the environment, but lead remaining in paint in older housing and in dust and dirt in many cities and suburbs continues to have subtle but profound effects on the health of children.

National Institute of Child Health and Human Development and the NIEHS supported research by scientists from the Harvard Medical School in infants born at the Brigham and Women's Hospital. They found that children born to mothers with higher blood levels had lower scores on standard tests for mental development and dexterity. However, the average blood lead levels in the mothers whose children were affected was significantly lower than levels now generally considered safe in adults. The implication of this study is that quite low levels of lead in pregnant women can effect the neuro-development of their children.

The Harvard scientists noted that many mothers in their study probably were exposed to lead during the restoration of their inner-city houses. This suggests that people who move to older neighborhoods and restore older houses must take special precautions to protect themselves from exposure to paint scrapings and carefully dispose of dirt and dust which accumulates during renovation.

Neurological deficits related to postnatal lead exposure were also observed in a large group of inner city children in Cincinnati. These children are participating in a study of lead effects supported by the NIEHS at the University of Cincinnati for almost a decade.

In these studies, the children had blood lead measured at less than 25 micrograms per deciliter. Current guidelines recommend that children tested in screening programs and found to have blood lead levels above 25 micrograms per deciliter should be referred for medical evaluation for lead poisoning according to the booklet, "Preventing Lead Poisoning in Children" published by the Centers for Disease Control in 1985.

A new test that measures postural sway or balancing ability is being developed and used by the Cincinnati group. Preliminary data indicate this to be a very promising technique to measure rapidly, objectively and in a non-invasive fashion the status of a child's central nervous system following lead exposure. As these pictures show, differences in motor skills between the children with lower levels of blood lead as compared to children with higher levels are obvious and striking. In the opinion of the experts at Cincinnati, the differences are most likely the result of neurologic damage due to lead exposure during very early childhood. Again, it needs to be pointed out that the levels of lead in the children with diminished motor skills were well below those, that up to now, have been thought not to warrant concern.

The reason I have emphasized the Harvard and Cincinnati studies is that they demonstrate the subtle harm done by very low levels of lead at the earliest stages of life. This emerging information has dire implications for the productivity and quality of life of thousands of children from our cities. This year we will support a much larger study in Yugoslavia designed to assess the effects of lead on pregnancy outcomes and to amplify the work done at Harvard and at Cincinnati. We hope that these studies can be used to better define levels of blood lead in mothers which affect neurologic development of the fetus and levels of medical concern in very young children. We will continue to study mechanisms by which lead does its damage and attempt to find more accurate, efficient, and economical methods to diagnose and treat lead exposures.

Many of the clues that led to these epidemiologic and clinical studies of the effects of lead exposure in children came from studies in laboratory mice and rats. Much of the research at NIEHS flourishes because of the close interplay between laboratory investigations and clinical studies.

Several years ago for example, researchers elsewhere noticed that certain tumors in persons with cancer contained activated oncogenies (substances in the genetic material which influence the reproduction of the cell) which were not activated in normal, non-cancerous tumor cells. Similar oncogenies were also identified in chemically induced tumors in laboratory animals. We are now studying oncogene activation in tumors in animals in our National Toxicology Program with the hope of being able to verify that the tumor in the animal was related to the chemical exposure, not some other factor. These studies have potential relevance to public health if we find that the process of oncogene activation and the development of cancer in people known to have been exposed to specific chemicals is found to mimic the process we are now finding in our animal studies.

Just as we know that oncogenes are involved in the biomedical process that stimulates cell growth, it has also been found that there is also biochemical regulation of this growth. "Tumor suppressor genes" have been found to be involved in the process of regulation. We have demonstrated that certain tumor suppressor genes are missing from tumor cells which have been chemically induced in laboratory hamsters. We created a new laboratory to follow up on this lead in another effort to understand the process of chemical carcinogenesis.

There are other examples of interesting and timely NIEHS basic environmental health sciences research efforts at NIEHS. For several years, I have reported the findings of the Six City Survey, an epidemiologic study of the health effects of exposure to common air pollutants. This study correlated increases in specific pulmonary effects in children when the levels of air pollution in their cities increased. The work of the Six City Survey is now ending and final results are being analyzed and readied for publication. However, the methodologies developed by the Six City Survey are being used in new epidemiologic studies of pulmonary effects of exposure to potentially toxic compounds in mists associated with acid rain. These studies of health effects of acid rain are just beginning, but should prove valuable in the assessment of the risks of acid rain on human health.

Another example of new NIEHS research comes from the recent report on the National Academy of Sciences on the toxicology of mixtures of chemicals. We are exposed daily to low levels of a number of chemicals in water and air, but extraordinarily difficult methodologic problems have discouraged toxicologists from attempting animal studies of the effects of mixtures. Instead, they focused on one chemical at a time. Now, encouraged by the Academy report which recognizes the problems but suggests that studies of mixtures may be scientifically defensible, we have published a peer-reviewed study protocol and intend to go forward with a toxicologic study of a mixture of 25 common ground water contaminants.

In summary, over the past year NIEHS has uncovered alarming new information about the effects of lead; we have embarked on new programs of research and training supported by Superfund; we are beginning to learn more about the health effects of acid aerosols as they relate to the problem of acid rain; we reorganized some of our intramural research laboratories to remain at the leading edge of science in the fields of genetics, molecular carcinogenesis and pharmacology; and we have increased our studies of reproductive toxicology. The NIEHS continues to be the leading Federal agency for the conduct of toxicologic studies of the chemicals to which significant numbers of citizens are exposed in the course of their daily activities.

Mr. Chairman, the NIEHS budget request for FY 1989 is $ 218,934,000. I wish there were time to discuss all these activities and the rest of the NIEHS research program with you in detail, but I am happy to be here to answer any questions you might have about our budget submission or about the environmental health sciences.

# BIOGRAPHY OF DR. DAVID P. RALL

August 3, 1926. Aurora, Illinois

Education: B.S. North Central College, 1946; M.S. (Pharmacology), Northwestern University, 1948; M.D., Northwestern University School of Medicine, 1951; Ph.D. (Pharmacology), Northwestern University, 1951.

Professional History: 1952-53, Intern, Bellevue Hospital. 1953-58, Scientist, Laboratory of Chemical Pharmacology, National Cancer Institute. 1958-63, Head, Clinical Pharmacology and Experimental Therapeutics Service, General Medicine Branch, National Cancer Institute. 1963-69, Chief, Laboratory of Chemical Pharmacology, National Cancer Institute. 1966-71, Associate Scientific Director for Experimental Therapeutics, National Cancer Institute. 1971-present, Assistant Surgeon General, USPHS.

Professional Organizations: American Association for the Advancement of Science, American Association for Cancer Research, American Public Health Association, American Society for Clinical Investigation, American Society for Pharmacology and Experimental Therapeutics, Society for Occupational and Environmental Health, Society for Risk Analysis, Society of Toxicology.

Honors, Awards: Editorial Board, Proceedings of the Society for Experimental Biology and Medicine, 1962-65. Member, National Institutes of Health Chemotherapy Study Section, 1965-67. PHS Meritorious Service Medal, 1966. Chairman, National Institute of General Medical Science Pharmacology Toxicology Review Committee, 1967-69. Editorial Board, Pharmacological Reviews, 1969-72. Chairman, DHEW Departmental Committee on Drug Research and Regulations, 1970. Associate Editor, Cancer Research, 1970-74. Chairman, OST-CEQ Ad Hoc Committee on Environmental Health Research, 1971-72. Adjunct Professor, University of North Carolina, Chapel Hill, 1972-present. US Coordinator, Environmental Health Program, US-USSR Health Exchange Agreement, 1972-present. Chairman, DHHS Committee to Coordinate Environmental and Related Programs, 1973-1985. Editorial Board, Archives of Environmental Health, 1973-76. Associate Editor, Journal of Toxicology and Environmental Health, 1974-78. DHEW Distinguished Service Medal, 1975. Member, DHEW Secretary's Review Panel on New Drug Regulation, 1975-76. Member, NAS Safe Drinking Water Committee, 1975-1977. Chairman, Committee on Health and Environmental Effects of Increased Coal Utilization, 1977-78. Member, Institute of Medicine, 1979-present. Editorial Board, American Journal of Industrial Medicine, 1980-present. Member, WHO Programme Advisory Committee, 1980-present; Chairman, 1980-81. Editorial Board, Risk Analysis, 1981-present. Editorial Board, Regulatory Toxicology and Pharmacology, 1981-present. Arnold J. Lehman Award, Society of Toxicology, 1983. Member, US Delegation to the US-Japan Cooperative Medical Science Program Committee, 1984-present. Member, Committee on Council Affairs, American Association for the Advancement of Science, 1986-88.

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### RADON

Senator CHILES. Are you doing anything on radon gas?

Dr. RALL. We are initiating some major epidemiological studies with new money provided by the Congress. Our research will concentrate on radon in the home. Most available health effects data come from studies of radon in uranium mine workers and in other settings where there is the likely synergistic effect between radon and particulate exposure.

There are existing cohorts of patients, people in areas where there is extensive residential radon exposure, and we think this will provide answers in 3 or 4 years.

### NIEHS FACILITY

Senator CHILES. Your Institute is the only one not located on the campus, but is instead located at Research Triangle Park in North Carolina. I understand the lease for your facilities expires in 1991.

Tell us what planning you are doing to assure that your continued space requirements are met.

Dr. RALL. We have used the NIH buildings and facilities appropriation to fund about $1.6 million to develop our plans for consolidating our entire operations in our current main headquarters 1 mile away from the temporary facilities. We expect to have $500,000 available this year; we will need $1.1 million next year. We are concerned that when our lease expires the Research Triangle Foundation will want to sell this very valuable piece of land which now has temporary buildings on it. It is very expensive for us to maintain this large number of small, inefficient, temporary buildings.

We would project a saving of close to $5 million a year by consolidating; the total cost of the project would be $50 million. Cost-benefit analysis suggests that we ought to move ahead as rapidly as we can.

### CHELATION THERAPY

Senator CHILES. Thank you.

In your lead studies, what ways have we come up with in order to treat children and people who already have this high body burden exposure of lead?

Dr. RALL. Particularly with adults who have high body burdens, chelation therapy, which is simply chemicals which sequester the lead and cause it to be excreted, is somewhat successful. This therapy is more difficult and potentially more dangerous with children and pregnant women. We have a number of research programs looking into this. We think, however, prevention is really the more important way of solving this important health problem.

Senator CHILES. What have you all done in regard, have you looked at chelation studies?

Dr. RALL. Oh, yes.

Senator CHILES. I mean, they are helpful?

Dr. RALL. They are helpful in the adult. It is dubious whether they are helpful in children. They are somewhat dangerous as they mobilize the lead, and although a lot is excreted, it also is easier to penetrate into the brain.

Senator CHILES. There are a lot of other claims of chelation studies.

Dr. RALL. Yes; there are.

Senator CHILES. What research have we done in regard to some of these the claims?

Dr. RALL. Well, our studies have not directly been involved in the other claims, but we have seen nothing in our studies to indicate that those claims would be validated at all. Perhaps some of the other Institutes——

Senator CHILES. Anybody else?

Dr. RALL. I would doubt it.

Chelation, if you do it vigorously, is really quite a heroic treatment.

Senator CHILES. I have people who write me and tell me if I had had chelation, I would never have had to have had a bypass.

Dr. RALL. You did the right thing.

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Senator CHILES. There are several questions for each of the Institute's that members of the subcommittee have and they will be submitted to you for your response.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

# QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

## CYSTIC FIBROSIS CENTERS

Question. Last year, the Committee directed that you fund various Cystic Fibrosis Centers. How many have you funded to date?

Answer. Currently, we are funding one Cystic Fibrosis Center at Case Western Reserve University which we have been supporting since 1983.

Question. How many do you plan to fund?

Answer. The FY 1988 Appropriation includes funds of $2,394,000 for the establishment of 2 or 3 new Cystic Fibrosis Centers. To date no awards have been made.

Question. What are your plans for expansion in FY 1989?

Answer. The 1989 budget request maintains our centers programs at the 1988 level.

## DIGESTIVE DISEASES RESEARCH

Question. Dr. Gorden, we are very, very pleased with the progress made by the NIDDK to establish and continue progress made by the Digestive Disease Centers Program. What areas in digestive disease and nutrition still need attention, and could be addressed within the Centers concept?

Answer. There are two areas in digestive diseases ready for development consistent with the level of effort required for a research center. These areas are: (1) research into pediatric gastrointestinal diseases (including liver disorders); and (2) research into pancreatic diseases and disorders. Nutritional research components to these centers would be encouraged.

Question. Last year, our Committee urged the NIDDK to devote as great a level of resources as possible toward increasing training opportunities in digestive disease research. What progress have you made in addressing the Committee's recommendations? If no significant progress has been made, would it be appropriate to designate a specific level of funding for this initiative?

Answer. NIDDK research training activities consist of two components. One is the National Research Award (NRSA) program of individual postdoctoral fellowships and institutional training grants. The second is the Career Awards Program.

There is an NIH and ADAMHA ceiling on NRSA support for research training. The NRSA allocation to NIDDK is divided proportionately among three NIDDK Divisions: Division of Diabetes, Endocrinology and Metabolic Diseases; Division of Kidney, Urologic, and Hematologic Diseases; and the Division of Digestive Diseases and Nutrition. The high priority needs and the opportunities for research training within each of these Divisions results in high competition for available NRSA funds from very creditable award applicants. Research training in digestive disease remains a high priority area for the Institute, and this field is being funded, as are those associated with the other two Divisions, at approximately the FY 1987 level. NRSA funds are sufficiently limited to preclude removing funds from one Division to the benefit of another Division of NIDDK. Available funds are being used for funding of the most highly rated applications. There are meritorious NRSA applications, currently unfunded, that would be funded were additional funds available.

The career award program supports Clinical Investigator Awards, Physician Scientist Awards, and Research Career Development Awards. In previous years there has been great fluctuation in the number of new awards that could be made in any particular year, reflecting funds available. These fluctuations could, in the case of digestive diseases, range from a low of 2 or 3 awards in one year to 17 or 18 in another. This resulted in serious confusion among potential applicants as to whether NIDDK did, or did not have a career award program. To overcome this problem, NIDDK has instituted a career award stabilization program, with a fixed number of new awards being made each year. The Division of Digestive Diseases and Nutrition will be able to award 9 new career awards each year within the stabilization program. This will result in a total program of 45 new and non-competing renewal career awards per year. This total of 45 active awards is a significant improvement over the totals of past years. The NIDDK career award stabilization policy provides a major improvement in the overall research training program for digestive diseases.

## BIOTECHNOLOGY RESEARCH

Question. During the past several years, new commercial opportunities have been created through developments in the field of biotechnology, including recombinant DNA, gene transfer, cell culture, monoclonal antibodies and bioprocess engineering. Please describe the biotechnology research NIDDK has funded during the past three years.

Answer. NIDDK has funded a broad range of research in biotechnology. These studies have used techniques such as recombinant DNA, gene transfer, and hybridoma technology to expand knowledge of and devise therapies for many diseases. A particularly exciting breakthrough in biotechnology resulted from a collaboration between a biotechnology company and scientists at NIDDK and the National Institute of Child Health and Human Development. Using recombinant DNA technology, these scientists were able to induce the production, in mouse milk, of tissue plasminogen activator (tPA), an agent used to treat heart attacks and blood clotting disorders. This technology is being used to explore the production, in animals, and subsequent extraction of large quantities of therapeutic proteins, which are now difficult and expensive to manufacture.

Recombinant DNA technology also made possible a landmark achievement in hematology research. NIDDK grantees cloned the gene for human erythropoietin, the major hormonal regulator of red blood cell production. This advance is enabling large-scale production of the hormone for therapeutic uses. The availability of erythropoietin is having a major impact on the treatment of anemia associated with end-stage renal disease.

Both intramural and extramural NIDDK researchers are creating insulin receptors with specific mutations to define receptor structure and function. These researchers have shown that the only function of insulin is to bind to and turn on its receptor. Mutant receptors can help define the parts of the receptor that are critical to its activity. This knowledge could provide insights into disease processes; for example, defects in such a region could underlie the development of diabetes.

Mutations that bring about the fatal metabolic disease, Tay-Sachs disease, cause the accumulation of metabolic waste products in cellular compartments called lysosomes. Research into the defective enzyme has become a model for understanding lysosomal enzyme biology, and recent research from the NIDDK intramural laboratories has revealed detailed information about the genetic defect of Tay-Sachs disease. These researchers have developed clones of the gene that is defective in this disease. Using these clones, they have found different defects in two population groups with high rates of the disease: Ashkenazi Jews and French Canadians. Finding two distinct defects enhances our ability to detect the disease and better define its cause.

NIDDK researchers have recently cloned the gene for angiotensin-converting enzyme, the key regulator of blood pressure in the kidney. The clone will enable further research into the structure and function of the enzyme and into the development of drugs to lower renal blood pressure -- now thought to be critical to preventing the progression of renal disease.

Intramural scientists have developed a model of progressive glomerulonephritis, a serious inflammatory condition of the kidney and one of the leading causes of end-stage renal disease. This model was developed using transgenic mice, which have both mouse and human genes. Researchers have shown that the introduction of a gene that induces cell proliferation leads to progressive kidney failure. The glomerular cells have been isolated from these mice, and studies are investigating the causes and consequences of cell proliferation and possibly of glomerulonephritis itself.

The emergence of hybridoma technology to produce monoclonal antibodies has created a wide range of therapeutic opportunities. Monoclonal antibodies are now benefiting kidney transplantation patients by enhancing the reversal of organ transplant rejection episodes. NIDDK grantees have successfully used monoclonal antibodies to inactivate cells that trigger rejection of pancreas transplants. Pancreas transplantation, still an experimental form of therapy, is now entering the initial period of human trials and may some day become a viable treatment for people with insulin-dependent diabetes.

Question. What biotechnology research is planned for the future?

Answer. NIDDK will continue to support research to develop therapeutically relevant uses for the new technologies emerging from the biotechnology revolution. Future studies will better define the benefits of using monoclonal antibodies in organ transplantation to prevent organ transplant rejection. As more specific products are developed, uses for these substances should grow for many types of tissue transplantation, including kidney, liver, and pancreas transplantation.

Monoclonal antibodies also show promise for blocking the destruction of insulin-producing pancreatic beta cells in diabetes-prone animals. This autoimmune process, now believed to underlie the emergence of insulin-dependent diabetes, is mediated by two types of immune cells. Researchers successfully eliminated these cells with monoclonal antibodies, greatly inhibiting the development of diabetes in these animals. Researchers have also found antibodies that are targeted specifically to beta cells in patients with insulin-dependent diabetes. Future studies will aim to devise tests for autoantibodies associated with beta cell destruction. These tests are important in insulin-dependent diabetes, in which beta cells are destroyed over an extended period of time. The ability to test for the disease before symptoms become manifest could halt the disease process by enabling early intervention before all the beta cells are destroyed.

Various groups of NIDDK intramural scientists are applying the latest tools of biotechnology to search for ways to combat the virus that causes the acquired immunodeficiency syndrome (AIDS). Scientists are creating mutant forms of the cellular receptor for human immunodeficiency virus (HIV) to learn how the virus binds to the cell. These studies could form the basis of a therapy for AIDS. Other researchers have identified parts of membrane of the cell nucleus that allow the virus to enter the nucleus, and have developed a monoclonal antibody that blocks the transport of the virus from the cytoplasm into the nucleus. Several groups of researchers are using the techniques of molecular biology to examine the regulation of expression of viral genes. Researchers who found a regulatory gene of a virus that does not cause disease in humans are determining whether that gene can block the expression of a critical HIV gene. Other scientists have found that HIV has similar regulatory elements as cytomegalovirus and that the two viruses may have similar controls. Sophisticated techniques developed for studying cytomegalovirus have now become potent tools for AIDS research. Investigators are using these methods to define precisely the regulation of expression of HIV in many types of cells. Other scientists have used recombinant DNA technology to devise a screening system for drugs to prevent the integration of the virus into the cell.

NIDDK-supported researchers are developing models for future gene therapy -- the substituting of normal genes for defective ones. Several research teams have successfully inserted normal genes into a mouse's own cells in vitro and then reintroduced the cells into the animals. Scientists are also working on improved vectors -- small chromosomes that serve as delivery agents for new genes. NIDDK grantees and intramural scientists have had encouraging results in developing several yeast and viral vectors, including a herpesvirus vector. Because the herpesvirus genome is large, researchers can use the vector to insert a large strand of DNA, enabling them to propagate large genes or gene clusters.

NIDDK grantees are actively taking part in the intense international search for the cystic fibrosis gene. New markers have been identified that are extremely close to the gene, now targeted to a small area on chromosome 7. Once scientists locate the gene, they will begin to explore its role in causing the disease, develop tests to identify carriers, and devise more effective therapies.

The ability to control the regulation of gene expression could usher in a new era in therapeutic intervention. Intramural and extramural scientists are studying the regulation of the globin genes, which regulate hemoglobin production. This research is determining the ways cells turn off their production of fetal hemoglobin and begin to produce adult hemoglobin, when a child is about six months old. Because the fetal hemoglobin gene is normal in sickle cell patients, the ability to prevent this switch from taking place could some day provide a therapy for people suffering from sickle cell disease.

A modification of an enzyme has helped to restore the immune systems of several children born with severe combined immunodeficiency disease. Devised through an SBIR grant to a biotechnology company, this method can be used to chemically alter the enzyme to keep it intact in the blood. Future studies may reveal this method to be a prototype for delivering missing or deficient enzymes to patients suffering from other metabolic diseases.

## TECHNOLOGY TRANSFER ACT OF 1986

Question. The Technology Transfer Act of 1986 provided that government-operated laboratories such as NIH could enter directly into cooperative research and development agreements with businesses and universities, and collect royalties from licensing of government-owned patents. Please describe the cooperative research agreements in which NIDDK scientists are participating in accordance with the Act.

Answer. At the moment, we are finding ourselves in the beginning stages of the implementation of the Act, and therefore the number of existing collaborative agreements is still relatively small. Once all of our scientists become acquainted with the opportunities provided by the new Act, the number of agreements covering such collaborative research and related activities is expected to expand considerably.

The existing agreements span a broad spectrum of topics. A number of these agreements cover situations where a pharmaceutical firm has requested NIDDK scientists to make available to it, for further research, unique chemical or biological substances which are not available elsewhere. In other cases, the roles are reversed and NIDDK scientists require unique substances which can be provided only by certain private sector firms. In some cases, a product of a particular industrial firm--and this could be either a drug or a therapeutic device--is being provided by its manufacturer for use in clinical trials organized by the Institute.

The ensuing agreements lay down the rules and terms for use of such unique materials or for collaborative research which would involve staff both from the Institute and the industrial firm. Usually, limitations of usage of a substance, future patent rights and shared publication of research results are a part of the language of such agreements, which varies depending on the nature of the issue at hand.

Question. How many dollars have been generated for NIDDK scientists and laboratories as a result of licensing agreements under the Act?

Answer. At the moment, we find ourselves still in the beginning stages of the implementation of this Act. There is growing interest among NIDDK scientists and laboratories and among their private sector counterparts in future collaborative efforts, which would result in the issuance of new patents. To date, no new funds have been generated as a result of licensing agreements, but we expect the situation to change once collaborative research activities expand and gain momentum.

Question. What steps has NIDDK taken to preserve the integrity of basic research and the Institute's mission while expanding the interaction with the private sector under the 1986 Act?

Answer. Because of the still limited extent of interaction with the private sector, such efforts have consisted primarily of a thorough indoctrination of the Institute scientists involved concerning their duties, responsibilities, and rights under the Act and under rules and regulations of the NIH. A thorough explanation of the patent process and related issues has also been found both necessary and productive. Doing this before actual agreements are drawn up has served to prevent misunderstandings and false expectations.

As of March 15, 1988 the NIH has formulated new rules and regulations which govern the drawing up and approval of cooperative research and development agreements and formulas for distributing shares of royalties and related income to NIH inventors. Under these rules, the proposed collaborative agreements are subject to central review at NIH. This new body of guidelines and regulations has been formulated to preserve the integrity of our basic research and the Institute's mission while encouraging and expanding our interaction with the private sector under the new Act.

## AIDS RESEARCH

Question. Please describe the research activities of the Institute that relate to AIDS.

Answer. The growing menace of the acquired immunodeficiency syndrome (AIDS) is a critical public health priority. NIDDK is forging a sizeable AIDS research initiative focused on areas of investigation relevant to its research programs. Information is urgently needed on the effects of the virus on parts of the body where the virus enters or does considerable harm, such as the digestive system, the urogenital tract, and parts of the endocrine system. A large intramural effort is exploring several areas of basic research to study mechanisms of viral expression in infected cells and to develop inhibitors to the human immunodeficiency virus (HIV).

The application of NIDDK intramural expertise in the fields of X-ray crystallography and nuclear magnetic resonance is making an important contribution to the fight against AIDS. These techniques allow the study of conformational states not demonstrable by any other means. Scientists are developing methods to create drugs against HIV, using these technologies to define the structure of inhibitors that bind the virus. Several viral proteins not found in human cells are ideal targets for antiviral agents.

Drugs that inhibit viral enzymes could interrupt the life-cycle of HIV. Researchers are attempting to develop agents that modify the active sites of two such enzymes. These inhibitors may themselves prove to be antiviral agents or could serve as valuable tools for defining the enzymes' active sites. Other scientists will use an identified agent that inhibits the virus by making the viral envelope fluid. Researchers will try to enhance this effect using novel membrane systems to disrupt the viral envelope by removing cholesterol.

Investigators are studying how molecules are transported through the cell in AIDS. They have found ways to retard the transport of the receptor to the cell membrane, have found an amino acid sequence needed to transport molecules into the nucleus, and have identified parts of the nuclear membrane that admit large molecules into the nucleus. Recently, these scientists have developed monoclonal antibodies that blocked viral transport. Other researchers are creating mutant forms of the cellular receptor of the virus to study the binding site of the virus. They have introduced genetic mutations into the receptor to alter its primary structure. These alterations could change the binding of the virus, creating a potential target for future drug therapy.

Several groups of scientists working in molecular genetics are advancing understanding of the regulation of viral genes. NIDDK intramural researchers are studying the regulatory gene of another virus to see if it can block the expression of a critical HIV gene. Other researchers have devised a system for screening drugs to prevent the integration of the virus into the cell.

DNA structure is a prime determinant of gene activity. Based on the expertise and knowledge developed through the study of globin genes, researchers are trying to identify the structural changes brought about by retroviral infection. This knowledge will define how sites on the virus alter the activity of host genes. Other researchers have found that HIV has similar regulatory elements as cytomegalovirus and may share control mechanisms. With techniques used to study cytomegalovirus, scientists are defining precisely the regulation of expression of HIV in many types of cells. Increased understanding of these processes could lead to new approaches to prevention or therapy for AIDS.

Hormones play important roles in regulating the immune system, pointing to the need to evaluate the endocrine status of AIDS patients. Work by NIDDK grantees in this area has uncovered relationships between hormone levels and disease status with important implications for the treatment and care of AIDS patients. In a study of patients with AIDS and with AIDS-related complex (ARC), scientists found subnormal levels of several adrenal hormones. However, in some of the AIDS patients and all of the ARC patients, the adrenal glands could be stimulated to increase hormone production. The discovery of adrenal deficiency in AIDS and ARC patients is significant because these hormones are necessary for the body to fight disease. As a result of these findings, AIDS patients can be evaluated for adrenal insufficiency and treated with the necessary hormones.

NIDDK is promoting research grant applications for studies of intestinal dysfunction in AIDS. This research area is important because the intestine both acts as a barrier against opportunistic infections and provides nutrition to the body. Damage to the intestinal tracts of AIDS patients can lead to severe malnutrition and a fatal wasting syndrome. Interruption of this vicious cycle of malnutrition and immune deficiency by total parenteral nutrition or other measures may reduce morbidity and provide an important advance in treating AIDS patients. A new area of investigation is emerging from the discovery that neuropeptides in the intestine can alter immune function and may be critical to regulating intestinal immunity. These substances play important roles in preventing infections that lead to intestinal damage. As studies reveal the mechanisms by which the immune system is altered, researchers may be able to develop drugs to modulate the effects of intestinal dysfunction in AIDS.

The possibility of HIV infection in the hemodialysis population is of concern because of the risks associated with exposure to blood products. Also, an increasing number of AIDS patients are developing end-stage renal disease. The Institute plans to sponsor research to increase understanding of AIDS-associated renal disease and to determine the incidence, risks, and effects of infection in hemodialysis and renal transplant patients.

One of the major routes of transmission of HIV is the urogenital tract. Research in this area is crucial to understanding the replication of the virus and, possibly, to developing treatment and preventive approaches for AIDS. NIDDK is encouraging research grant applications for studies aimed at understanding how the lower urinary tract harbors, promotes replication, and transmits HIV. NIDDK is also promoting research on the effect of HIV on blood-forming cells -- vital knowledge for treating and preventing AIDS.

Question. How has NIDDK coordinated its activities with those of other Institutes?

Answer. NIDDK is actively participating in activities related to the acquired immunodeficiency syndrome (AIDS) that are coordinated by the National Institutes of Health (NIH). The Institute Director is a member of the NIH AIDS Executive Committee. Additionally, the Institute contributes regularly to the NIH-wide bimonthly AIDS science report. This document updates information on scientific advances in AIDS-related research conducted by the institutes.

A recently published joint request for application (RFA) between NIDDK and the National Heart, Lung, and Blood Institute represents a collaborative effort into AIDS research. This RFA is designed to expand research into the suppressive effects of the human immunodeficiency virus (HIV) on the blood-producing cells of the bone marrow.

The Institute was allocated a large share of the funds administered by the Office of the Director, NIH, for conducting intramural research into developing antiviral agents. Thirteen intramural laboratories are now applying their expertise in such areas as structural biology, molecular biology, chemistry, cell biology, enzymology, and immunology to search for agents against HIV. An NIDDK intramural scientist serves as the coordinator of NIH-wide intramural efforts funded by the Office of the Director, NIH.

One NIDDK intramural research team is developing a much needed protein resource that will soon be available to all AIDS researchers at NIH. These scientists cloned the gene for a critical HIV gene, which is now being purified for large-scale production.

## USE OF IMMUNOSUPPRESSIVE DRUGS

Question. During the past year, progress in the use of immunosuppressive drugs in the treatment of Type I diabetes has been widely reported. In particular, cyclosporine has reportedly increased the rate of remission of diabetes. However, cyclosporine is a relatively costly drug and has many known serious side effects because of its broad immune-system suppressing effects. Please describe the NIDDK research underway which focuses on the use of immunosuppressive drugs in the treatment of diseases believed to be of autoimmune etiology.

Answer. Type I, insulin-dependent, diabetes mellitus is now thought to be largely autoimmune in origin with destruction of the pancreatic islets by the body's own cells. Several animal models have been developed for this disease process, in particular the NOD mouse and the BB rat. Two NIDDK supported researchers, Drs. Like and Rossini at the University of Massachusetts, have shown cyclosporine inhibits the development of diabetes in these animal models. Although we are not supporting any studies of classical immunosuppressive drugs, including cyclosporine, in the prevention of diabetes mellitus in humans, we are funding Dr. Skyler at the University of Miami to do ancillary studies on the immune function of patients enrolled in a Sandoz funded clinical trial of cyclosporine for prevention of diabetes.

We have several researchers looking at the potential of directly modulating the immune system to prevent the development of diabetes mellitus. Dr. Fathman at Stanford University recently showed that development of diabetes in the NOD mouse could be prevented by treatment with a monoclonal antibody that specifically inactivates a subgroup of lymphocytes. Most remarkable was that as well as halting the development of the disease acutely, the mice remained free of disease even after stopping the treatment.

In the broader context of immunotherapy of diabetes, we have several researchers looking at immunomodulation therapy in relation to transplantation of pancreatic islets. Although this work is mainly in animals the hope would be to develop a therapy that would obviate the need for long-term immunosuppression of the transplant recipient and also enhance the initial and long-term survival of the transplanted tissue.

Although no one expects to use immunotherapy to prevent autoimmune thyroid disease since it is a relatively easily treated disease, Dr. Vladutiu at SUNY, Buffalo, is investigating the use of specific antibodies to prevent the development of experimental autoimmune thyroiditis. These experiments should better define the role of autoimmunity in autoimmune thyroid disease and potentially other autoimmune diseases.

Question. Please describe any research underway which may aid in controlling the side effects and cost of immunosuppressive drugs.

Answer. Although we do not support research specifically looking at the side effects or costs of immunosuppressive drugs, several of the creative immunotherapy regimens previously mentioned are specifically directed at avoiding the side effects of drugs by not requiring their use or using them only outside the body. Particularly interesting is Dr. Fathman's study where transient treatment of the mice with antibodies led to long term remission of the disease.

## DIABETES RESEARCH

Question. Some diabetes researchers have reported that 60 percent of Type I diabetes cases and up to 95 percent of diabetes cases worldwide are environmentally determined and, thus, potentially avoidable. Some have argued that diabetes research has focused too heavily on possible genetic causes of diabetes, and has neglected such environmental factors as infectious agents which may explain the patterns of disease that have been observed. Other scientists believe that it is too early to ascribe these patterns to environmental causes. Please describe the research activities of NIDDK that relate to possible environmental causes of Type I and Type II diabetes.

Answer. The research activities funded by NIDDK that can be classified as relating to environmental causes of diabetes are extensive and too numerous to be described individually. However, it is impossible to separate environmental effects from the genetics of diabetes. Clearly, the environmental milieu that a given genetic set, including predisposition to diabetes, resides in has a marked effect on phenotypic expression. To emphasize this point is the well-known fact that not all individuals with genes that can lead to diabetes, in fact, express the diabetic trait. The most striking example of this is the finding that among identical twins when one of the twins becomes diabetic the other twin may not contract the disease. This is unlike the situation for Tay-Sachs disease, for example, where the environment has no apparent effect on expression of the disease.

Given this caveat described above, it is possible to categorize those grants whose main emphasis is the environment. into subsets that include effects of obesity and physical fitness, acculturation, and viruses and to summarize representative work from each group.

Obesity is a major risk factor for becoming diabetic. This is true during pregnancy as well. This form of diabetes is called gestational disease. At present, no animal model exists for this disease that has a significant health impact on the offspring and the mother. A group of researchers investigating this diabetic syndrome is developing an obesity model in rats that becomes diabetic during pregnancy. They are examining the fat cells in these animals and have developed the hypothesis that enlarged adipose tissue mass is the major etiologic factor in developing gestational diabetes.

Another group of investigators is examining the role of obesity in Type II diabetics by studying the effects of weight loss induced by gastric by-pass surgery in morbidly obese diabetics and nondiabetics.

The finding that second generation Japanese Americans (Nisei) have high prevalence rates of Type II diabetes is ascribed to acculturation. These rates have been studied in comparison with native Japanese or U.S. Caucasians. The data suggest that Japanese men may have an inherent tendency to develop diabetes and that these conditions become frequent when certain "environmental" variables intervene. Some of these variables are diet, health habits, psychosocial stress, and cultural factors. These factors likely influence the development of a certain type of adiposity that leads to Type II diabetes as well as the complications of diabetes. This project is being expanded to include Nisei women as well as third generation Japanese Americans.

In the field of virology, research has been initiated on a project to expand a prospective study relating to the incidence of islet cell damage and glucose intolerance in offspring exposed to rubella (measles) in utero. This exploits the finding that IDDM is frequently seen in children who experienced congenital rubella infections during the 1964-65 pandemic.

Question. Please provide data which compare the amount of research funding that related to possible environmental causes of diabetes with that relating to possible genetic causes of diabetes.

Answer. The categorization of research funding into genetic and environment studies is not straightforward since these issues are not freely separable on a scientific level. Most research in this area rightfully explores the interplay of these factors. Nonetheless, we can arbitrarily divide the studies based upon the predominant emphasis. Where no obvious emphasis could be determined, we have proportioned the funds according to the scope of the research effort in each of the categories.

Using this method, we can estimate that in FY 1987 this Institute supports 19 research projects at a total cost of approximately $3.1 million with a genetics predominance and 34 projects at a total cost of approximately $7.6 million with an environmental predominance.

Question. Please address the criticism made by some scientists, that too little research has been directed toward understanding possible environmental causes of diabetes.

Answer. The NIDDK has as one of its missions fostering the discovery and application of new knowledge about diabetes for the alleviation of human suffering caused by this disease. It is clearly apparent to biomedical scientists familiar with this field that there are important genetic and nongenetic (environmental) influences on the appearance, natural history and response to therapies of this disease in patients. As we have learned more about diabetes (and most other chronic diseases), we have come to appreciate the inseparability of genetic and environmental factors. The impacts of toxic exposures, infectious agents, nutrition, lifestyle, etc., need to be evaluated in the context of the genetic susceptibilities of the individuals or populations of interest. Likewise, genetics alone cannot completely account for the behavior of this disease. For example, the causal role of obesity (an environmental factor) on the development of diabetes varies across racial/ethnic lines (a genetic factor) with Native Americans apparently most susceptible. However, this strong genetic predisposition seems to be suppressed in those individuals who maintain normal weight.

As I have just described to you, we do, in fact, support a large amount of research on the possible environmental causes of diabetes. However, scientific progress is rarely made in a straight line from question to answer. The researcher is constrained by the available methodologies. The recent development of incredibly powerful tools of genetic analysis and experimental manipulation have opened an entire vista of research questions and answers that were, heretofore, impossible to see. The diabetes research community has just begun to capitalize on this opportunity. It is erroneous to contend that this fresh enthusiasm for genetic-based research is somehow obscuring the multifaceted nature of diabetes causation. In fact, such research holds the potential for clarifying the nature of nongenetic factors in this disease as well as genetic ones.

## HUMAN GENOME

Question. During the 100th Congress, significant attention has been paid to proposals to increase the Federal commitment to mapping and sequencing the entire human genome. Some of this interest has focused on the potential of such an effort to stimulate "competitiveness" of U.S. biotechnology companies by expanding the basic science foundation for the development of new health products such as diagnostics and treatments. NIDDK has long funded research to locate genes that are involved in such diseases as cystic fibrosis, Tay-sachs disease, polycystic kidney disease and diabetes mellitus. Please discuss the commercial potential of the genetic information that has been obtained through NIDDK-funded research related to the above listed or other important diseases?

Answer. Substantial commercial potential is emerging for information obtained from genetic research funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). Commercializable medical applications range from developing diagnostic tools on the basis of isolated genes, to developing human therapeutic agents and avenues for gene therapy. This research has and will increasingly yield directly marketable products and accelerate the development of products. These products may eventually make possible the control of many human diseases.

Anticipating the potential commerical value of their original research, NIDDK intramural and extramural scientists have filed a number of patent applications. These applications relate to commercially useful advances in state-of-the-art technologies developed under the auspices of the Institute. One patent application resulted from an exciting collaboration between a biotechnology company and scientists at NIDDK and the National Institute of Child Health and Human Development, leading to a major advance in genetic engineering. In mouse milk, using recombinant DNA technology, scientists induced the production of a therapeutic agent called tissue plasminogen activator (tPA). These studies are developing a method for producing therapeutic agents that are now difficult and expensive to manufacture. The technique will eventually be applied in larger animals for producing and extracting large quantities of such drugs to reduce the cost and increase the efficiency of their production.

Intensive academic and privately sponsored research, on an international level, continues in quest of identifying the cystic fibrosis gene. NIDDK supports researchers who are among those actively taking part in this exciting search. As new genetic markers are found, scientists are succeeding in homing in on the gene. Determination of the precise location of the gene will enable the development of diagnostic tests to identify carriers and contribute to more effective therapies to combat cystic fibrosis.

A seminal achievement in the commercialization of hematology research arose from a collaboration between NIDDK grantees and a biotechnology company. As a result of these efforts, researchers cloned the gene for human erythropoietin, the major hormone that regulates the production of red blood cells. These studies have enabled large-scale commercial production of the hormone for therapeutic uses. Erythropoietin is now being used to treat anemia associated with end-stage renal disease.

NIDDK researchers have recently cloned the gene for angiotensin-converting enzyme, the key regulator of blood pressure in the kidney. The clone will enable further research into the structure and function of the enzyme and into the development of drugs to lower renal blood pressure -- now thought to be critical to preventing the progression of renal disease.

NIDDK intramural scientists are extending their expertise in genetics to search for anti-human immunodeficiency virus (HIV) agents. HIV is the virus that causes acquired immunodeficiency syndrome (AIDS). Using genetic engineering techniques, one group is creating mutant forms of the HIV receptor on human cells to learn how HIV gains entry into the cell. These studies could lead to a therapy for AIDS. Another group has used recombinant DNA technology to devise a screening system for drugs to prevent the integration of the HIV into the cell. Drugs are now being screened using this system.

Studies into the regulation of gene expression offer an approach to modulating the control of the activity of critical genes. Both intramural and extramural NIDDK scientists are studying the regulation of globin genes, which regulate hemoglobin production. Scientists are exploring how cells turn off their production of fetal hemoglobin and begin to produce adult hemoglobin, when a child is about six months old. Because the fetal hemoglobin gene is normal in sickle cell patients, the ability to control this switch may ultimately provide a therapy for sickle cell disease.

Question. Please discuss the mechanisms in place at NIDDK that will facilitate rapid technology transfer and commercialization of genetic information.

Answer. NIDDK has in place several mechanisms for rapid technology transfer and the commercialization of genetic information. The primary avenues of information dissemination exist through publication in the scientific literature, participation in scientific conferences, and through press releases and press conferences. The results of Institute-sponsored and conducted research are widely published in the scientific press. Additionally, NIDDK scientists and grantees attend scientific conferences at which they exchange information with many scientists, including those who represent the private sector. Through press releases, the Institute communicates with a large, diverse audience, including science writers. This year, several press releases describing advances in genetic research were widely publicized in the lay press, and the Institute participated in a major press conference on the genetically engineered production of tissue plasminogen factor (tPA) in mouse milk.

Through several collaborative research ventures with biotechnology companies, Institute researchers and grantees have developed products that have commercial application. One patent application resulted from a collaboration between between a biotechnology company and scientists at NIDDK and the National Institute of Child Health and Human Development, leading to a major advance in genetic engineering. These scientists induced the production of a therapeutic agent -- plasminogen activator (tPA) -- in mouse milk. As a result of another collaboration between NIDDK grantees and a biotechnology company, researchers cloned the gene for erythropoietin, the major hormone that regulates the production of red blood cells. These studies have enabled large-scale production of the hormone for therapeutic uses. An SBIR grant to a biotechnology company led to the development of a method of altering enzymes, which has provided a novel experimental therapy for several children suffering from a genetic form of immune deficiency. The company devised a way to keep the enzyme intact in the blood, a method that may prove useful for delivering enzymes that are defective in other metabolic diseases.

Another resource for promoting technology transfer and commercialization centers on NIDDK's participation in the consensus development process. An important function of consensus conferences is to disseminate information on treating diseases and using new technologies. The Institute has conducted several consensus conferences during the past few years. These include conferences on the role of diet and exercise in the management of Type II (adult-onset, insulin-independent) diabetes, research directions in osteoporosis, and the prevention and treatment of kidney stones. The Institute is also sponsoring a series of colloquia on the possible contribution of interdisciplinary research, including genetic research, to the study of diabetes.

In addition, NIDDK participates in coordinating and fostering activities related technology transfer and commercialization of scientific information through its Office of Disease Prevention and Technology transfer and via its membership on the Coordinating Committee on the Assessment and Transfer of Technology, and the NIH Working Group on Mapping and Sequencing the Human Genome.

## INFLAMMATORY BOWEL DISEASES

Question. Chronic inflammatory bowel diseases, especially Crohn's disease and ulcerative colitis, incapacitate several million Americans, including thousands of children. Could you please tell us what progress is being made in research on Inflammatory Bowel Diseases at your digestive diseases center at Harbor General-UCLA Medical Center?

Answer. Research advances in Inflammatory Bowel Disease (IBD) attributed to the IBD Center fall into two major categories; namely, genetic epidemiological approaches to defining the genetics of IBD, and research studies of the immune system.

One genetic study at the Center identifies a genetic etiology of IBD through the use of genetic markers. The marker system used is identified with the disease in a greater frequency than would be expected by chance alone. Two different polymorphic patterns in IBD patients have been detected using the marker technique. Further studies are to include genetic phenotypic approaches and physiologic and immunologic abnormalities in the clinically unaffected relatives of patients with IBD. These preliminary results are among the first to show a possible genetic connection to IBD.

Immune system abnormalities in IBD are studied at the Center to demonstrate the association of these abnormalities with IBD activity and alteration of these abnormalities upon immunosuppressive therapy - specifically using 6-mercaptopurine and cyclosporine. Of special note is the work that shows that certain neuropeptides modulate the response of the immune system. Some enteric neuropeptides apparently regulate the inflammatory response as well as the function of certain sub-sets of immune cells within the mucosal compartment. These results and observations seem to indicate that the control of the immune system, with respect to IBD, may be regulated using a variety of biologically active compounds including neuropeptides.

## SLEEP RESEARCH

Question. Dr. Goldstein, the NINCDS through its Convulsive, Developmental and Neuromuscular Disorders program conducts research on sleep disorders such as narcolepsy. How can the NINCDS continue to develop a strong program in basic sleep research, and in related disorders such as narcolepsy?

Answer. The NINCDS continues to develop a strong program in sleep research and disorders of sleep by participating in the Trans-NIH Sleep Research Coordinating Committee, by issuing program announcements soliciting research in promising research areas, and by funding investigator initiated research of high merit recommended for support by the National Advisory Neurological and Communicative Disorders and Stroke Council.

Question. Most narcolepsy research is conducted through the epilepsy branch. Years ago, many believed that since narcolepsy and epilepsy patients displayed paroxysmal similar symptoms, that a link existed between these two disorders. Now it is generally agreed within the scientific community that the physiologic basis of narcolepsy is quite distinct from that of epilepsy and that treatment techniques are vastly different. How could NINCDS address this distinct difference with the current structure?

Answer. Because the NINCDS is responsible for support of research in more than 650 different neurological and communicative disorders, it is not possible to assign responsibility for each disorder to a different staff person. Areas of responsibility are assigned to staff depending on their areas of expertise and research interests. The grant portfolios for narcolepsy and epilepsy are administered within the Epilepsy Branch for administrative convenience only.

Question. Could a separate branch on sleep, or narcolepsy be established?

Answer. Establishment of a separate branch for sleep disorders is possible, however to establish separate branches for each neurological or communicative disorder would become administratively cumbersome. Sleep research is well supported through the current administrative structure.

## HUMAN FETAL TISSUE RESEARCH

Question. NIH currently supports a number of research projects which make use of human fetal tissue and cells. This research may lead to beneficial treatments for many human disorders including Parkinson's disease, Huntington's disease, Alzheimer's disease, and spinal cord injury. However, the use of tissue from human fetuses raises serious social and ethical concerns among policy makers, the general public, and others. What types of research projects, if any, is your Institute currently supporting in this area?

Answer. Several studies supported by the NINCDS use human fetal tissue as a component in basic research into the biochemical, molecular, and genetic mechanisms which produce aberrations of the normal developmental process, resulting in severe birth defects, handicaps, and genetic anomalies which often lead to death. Fetal tissue is also being used to seek a better understanding of the mechanism by which HIV infection produces neurological problems in AIDS patients. In addition, research is designed to seek ways to reverse degenerative disease processes, or ameliorate morbidity in severe, permanent trauma injuries, particularly of the head and spinal cord. In other basic research, investigators are focusing on the molecular interactions between glial cells and their infection with a neurotropic virus which culminates in demyelination in the human brain, usually in an immunocompromised patient.

Question. What is the source of the tissue or cells used for this research?

Answer. The fetal tissue used in this research is obtained from universities, or hospitals and clinics performing abortions. There is no contact between the patient and the investigator conducting the research, and no payment is made to the woman who donates the fetal tissue. Human fetal cells used for research are obtained during routine amniocentesis.

Question. Do you anticipate increasing the level of support for this type of research as a result of the apparent success with neural fetal transplants by researchers in other countries?

Answer. The Assistant Secretary for Health has initiated a moratorium on research in this area pending an assessment of certain ethical issues. In the interim, the Institute is closely following foreign efforts in this area to assess the state of the art. Determinations on the level of support for research involving implantation of fetal tissue will depend upon the outcome of the ethical discussions, the state of research opportunities and the receipt of highly meritorious research grant proposals.

Question. What type of review would a research proposal that involved the use of human fetal tissue be given if funded by your Institute?

Answer. Any proposal submitted to the NIH involving human subjects must include a cerification that the applicant institution's Institutional Review Board (IRB) has reviewed the proposal and approved its protocol for the use of human subjects. Once a proposal is submitted to the NIH and its research is considered relevant to the mission of one of the Bureaus/Institutes/Divisions (BIDs), it then receives a dual peer review according to established NIH guidelines. While the primary focus of peer review is on scientific merit, the reviewers are asked to comment on any issues raising ethical concerns with the use of human subjects. For applications assigned to the NINCDS, any such concerns raised by the inital peer reviewers are brought to the attention of the NINCDS' Advisory Council. If the proposal is to be funded, these concerns must be addressed and eliminated prior to the funding of the proposal. A funded proposal is assigned to a Health Scientist Administrator within the BID who is responsible for reviewing the annual progress report and certifying that support of the project continues to be appropriate, including the use of human subjects. In the case of special areas of research such as those involving human fetal research, other appropriate offices are contacted prior to funding the proposal. These offices would include, for example, the Office of the Director of NIH and the NIH Office of Protection from Research Risks.

## BIOTECHNOLOGY

Question. Recombinant DNA (deoxyribunucleic acid) technology and other molecular biology techniques already has had an immense effect on learning about central nervous system (the brain and spinal cord) disorders. This information has been applied to the clinical setting for individuals with some neurological disorders, e.g., Guillain-Barre syndrome. Would you briefly highlight some of the recent advances achieved by your Institute which was made possible by these technologies.

Answer. On the basic level, recombinant DNA technology is currently employed to determine which genes are actually expressed in the nervous system. Although most of the synthesized proteins are similar or identical to those found in other tissues, some proteins appear to be uniquely present in nervous tissue. These are being identified, and their cellular distribution charted. Possibly these proteins will be associated with certain functional properties of nerve cells such as learning and memory.

Molecular genetic techniques have been employed to study familial Alzheimer's disease, sporadic Alzheimer's disease, and Huntington's disease with dramatic results and important implications for early diagnosis and understanding mechanisms of these diseases. Recent studies have shown that an autosomal gene defect which causes an early onset form of familial Alzheimer's disease and the gene coding for the abnormal amyloid protein found in this disease are located at different positions on chromosome 21. Several new genetic markers for Huntington's disease have been located on chromosome 4. The current studies show that a rare, ancient, and single gene mutation is responsible for the disease and either a single or double dose of the gene produce equal severity in the symptoms.

The gene for Duchenne muscular dystrophy has been precisely located on the X chromosome. NINCDS supported scientists have recently determined an entire coding sequence and discovered a protein dystrophin, produced by the the normal gene. Dystrophin is present in extremely small quantities in normal muscle cells, but not in muscle cells of Duchenne muscular dystrophy patients.

NINCDS grantees have mapped the gene for von Recklinghausen neurofibromatosis, (NF-1), to the short arm of chromosome 17, and have identified the primary defect in bilateral acoustic neuroma, (NF-2), to loss of genes on chromosome 22. It appears that the defect on chromosome 22 in NS-2, and some other common tumors of the CNS, involves the inactivation of a tumor suppressor gene. The immediate issues that must be addressed for NF-1 and NF-2 are the possibility of genetic heterogeneity among families and the identification of useful DNA markers closely flanking the genes.

Other recent advances in this area are:

The structure of basic myelin protein has been determined and several laboratories are using appropriate probes to investigate its development, regulation and role in demyelinating disorders.

The gene for the enzyme deficient in Gaucher's disease has been cloned and means for introducing the appropriate mRNA into sites where the enzyme must be replaced are being explored.

An antibody ELISA spot test has been developed to diagnose early AIDS infection in newborn children and to detect early invasion of the nervous system by AIDS virus.

Question. What role is your Institute playing in transferring these basic research findings to the clinical setting?

Answer. Several basic research findings have immediate and direct clinical research applications. For example, at the University of Iowa's Department of Neurology, an extensive program has delineated the changes in the brains of patients with Alzheimer's Disease; much of the research has involved a monoclonal antibody and other neurochemicals. A part of the hippocampal formation appears to be partially susceptible to destruction. Several investigators believe they have identified a substance, and its locus of action in the hippocampus, which is of great importance in the development of memory in mammals. A "receptor" on nerve cells for a form of aspartate is involved; on the basis of this knowledge, pharmaceutical companies are searching for drugs which could augment or block the activity of the neurotransmitter. These may possibly improve memory; it may also minimize damage due to convulsions.

In studies of Huntington's disease, field trials of a presymptomatic test for Huntington's disease are continuing at both Huntington's Center locations in Boston and Baltimore. This work will serve as a model for the development of standardized presymptomatic tests for other neurological disorders with a genetic basis such as familial Alzheimer's disease, Tourette's syndrome, and some forms of ataxia. Also, the NINCDS is promoting the application of basic research findings to clinical applications by sponsoring NIH Consensus Development Conferences, i.e., Consensus Conference on Neurofibromatosis.

Question. With respect to biotechnology research, what kind of collaborative arrangement, if any, do you have with the other Institutes and/or Federal Agencies, and the private sector?

Answer. The NINCDS has jointly sponsored with other NIH Institutes, program announcements soliciting research applications in the area of biotechnology. The NINCDS also utilizes the Small

Business Innovative Research Program to collaborate with the private sector in the development of new biotechnology.

## AIDS

Question. The human immunodeficiency virus (HIV) infects the central nervous system of many AIDS victims. In fact, recent studies indicate that neurological and behavioral abnormalities may be the first symptoms, and in some cases the only symptoms of HIV infection. NINCDS currently supports numerous research projects aimed at finding the mechanisms of HIV infection in the CNS, as well as at searching for a treatment for this deadly virus. Describe some of the neurological and behavioral symptoms that have been observed in individuals infected with the HIV virus.

Answer. Early reports indicated that perhaps a third of AIDS patients developed progressive dementia late in the illness. It is now becoming apparent that varied expressions of involvement of the central and peripheral nervous systems are even more common. In some reported series of cases, as many as 75-80% of AIDS patients have neurological symptoms sometime during the course of the disease. These symptoms vary from patient to patient and depend upon which part of the nervous system is affected. Impaired memory and concentration, slowing of movement, tremor, ataxia, and weakness of the legs are often seen in patients when AIDS involves the nervous system.

Question. How soon after infection are these abnormalities observed?

Answer. Symptoms of neuro-AIDS have been reported to occur within days or weeks to five or more years after putative initial infection with the HIV agent, and may be the initial indication of disease.

Question. Since neurological and behavioral abnormalities sometimes are the only symptoms demonstrated by an HIV-infected individual, would you recommend that psychological tests by administered to high-risk groups of the population?

Answer. Since reliable and universally acceptable AIDS-specific diagnostic neuropsychological tests are not available, nor does early detection yet lead to specific treatment, widespread across-the-board testing of subjects at risk for AIDS is not regarded as cost-effective at this time.

## HEAD INJURY

Question. NINCDS will act as the lead agency in an Interagency Head Injury Task Force. It is anticipated that this task force will address the research, training and service delivery needs related to traumatic head injury, a serious public health problem in the United States. Rehabilitation research and programs should be one of the subjects considered by this task force, and representatives from both the Department of Health and Human Services and the Department of Education should be involved in addressing these concerns. What progress has been made in establishing this task force?

Answer. The Interagency Head Injury Task Force has been established by the Secretary of Health and Human Services; the Director, NINCDS, NIH, has been appointed as Chairman; and members of other agencies have been appointed. The Task Force has met on two occasions in order to define its task, outline its activities, and develop three subcommittees to address important issues in head injury research, clinical care, and community activities. The Committee intends to hold public hearings in the Fall and prepare a report of its activities and recommendations.

Question. Are you currently involved in any studies with the Department of Education related to this subject?

Answer. The National Institute of Neurological and Communicative Disorders and Stroke coordinates its rehabilitation research activities with the Department of Education through the National Institute on Disability and Rehabilitation Research. The Director, NINCDS, serves on the Interagency Committee on Handicapped Research. Staff of both Agencies meet formally and informally for the purposes of continued close cooperative activities. In addition, a member of the National Institute on Disability and Rehabilitation Research has been appointed to the Interagency Head Injury Task Force.

Question. What is the status of our knowledge about reversing brain damage in head-injured individuals?

Answer. It is believed that death of nervous tissue after traumatic injury may occur, at least in part, because large amounts of calcium enter damaged cells. Investigations are underway to prevent this uncontrolled calcium flux by treatment with gangliosides, magnesium, or drugs that block calcium channels in the cell membrane, such as verapimil. These studies are at very early stages; behavioral correlations with treatment are planned for the future if promising morphological changes are seen.

Investigators have also demonstrated that head-injured animals treated with gangliosides, a class of complex molecules containing lipid and sugar residues that are found in nerve cell membranes, perform better in behavioral paradigms than do untreated controls.

Scientists have demonstrated, with experimental models, that implants of neural tissue can reverse the behavioral effects of lesions in certain areas of the brain. Encouraging results have also been obtained using implants of adrenal medullary cells. It appears that restoration of the structure of the injured brain--the goal of implantation of the neural tissue--may not be necessary, and a supply of trophic substances may promote survival of injured nerve cells.

Clinical investigators have completed a controlled clinical trial that has demonstrated the efficacy of high doses of barbiturates for the management of severely head injured patients who have uncontrolled increasing intracranial pressure. Increased intracranial pressure is a serious, life-threatening complication of severe head injury. This study has also demonstrated the importance of the management of hypotension (low blood pressure) and other risk factors during the early stages of head injury.

## GROWTH HORMONE AND CHILD DEVELOPMENT

Question. There are more than one million children in the United States who fall below the third centile of height for their age. Fewer than one in every hundred of these children is receiving human growth hormone because of limited availability of the hormone. Is limited availability the only reason?

Answer. No. Clinical considerations have now become paramount in determining which short children should receive growth hormone therapy, and the supply of the hormone is no longer a consideration in determining its use.

The supply of human growth hormone extracted from cadaver pituitary glands was the limiting factor in the distribution and use of this important therapeutic agent prior to October, 1985. Since then methionyl-human growth hormone has been manufactured biosynthetically and marketed by Genentech, Inc., and since April, 1987, biosynthetic human growth hormone has been manufactured and marketed by Eli Lilly and Co. as well. The important issue has now become ascertaining as precisely as possible which short children will benefit from growth hormone therapy. Studies are now in progress that will generate this necessary clinical information.

Question. Is the cost of the drug so prohibitive that parents of growth retarded children are unable to pay for growth hormone?

Answer. Growth hormone therapy is expensive. A year's treatment with either of the two biosynthetic products now marketed in the United States costs between $10,000 and $15,000. However, both Genentech, Inc. and Eli Lilly and Co. have in place a guaranteed indigent care program by which no patient who needs biosynthetic methionyl-human growth hormone or biosynthetic human growth hormone, respectively, will have to go without it because of an inability to afford the cost of therapy.

Question. Is human growth hormone not indicated for treating some growth retarded children?

Answer. It is currently thought that only some children who fall below the third centile of height for age will benefit from growth hormone therapy. For unknown reasons the majority of extremely short children appear to have sufficient quantities of circulating growth hormone as detected by radioimmunoassay. Whether their growth hormone is as biologically potent as the circulating growth hormone of taller children remains to be determined. Several clinical trials are now in progress to ascertain what percentage of the non-growth-hormone-deficient short children will respond favorably to the administration of biosynthetic human growth hormone or biosynthetic methionyl-human growth hormone. Preliminary data indicate that about 25 percent of these children do not respond to growth hormone therapy and that the growth response of another 25 percent is negligible. However, about 50 percent of these short children do show improved rates of growth. It remains to be determined if their final height attainment will also improve on this therapy.

## HUMAN FETAL STUDIES

Question. NIH currently supports a number of research projects which make use of human fetal tissue and cells. This research may lead to beneficial treatments for many human disorders including Parkinson's disease, Huntington's disease, Alzheimer's disease, diabetes, and spinal cord injury. However, the use of tissue from human fetuses raises serious social and ethical concerns among policy makers, the general public, and other. What types of research projects, if any, is NICHD currently supporting in this area?

Answer. The NICHD supports research that will lead to reduced infant mortality, to freedom from the threat of life-impairing diseases and disabilities, and to fulfilling the expectation of planned, uncomplicated pregnancies resulting in the birth of healthy babies. As a part of this effort, the Institute supports biochemical, physiological, genetic and nutritional research involving human fetal tissue. Examples of this research include:

- New techniques are being developed which may enable earlier prenatal diagnosis of inherited metabolic disorders. Possible methods include (1) establishing direct, rapid, accurate assays for elevated levels of diagnostic compounds in amniotic fluid, avoiding the time and cost of culturing amniocytes; (2) assaying enzymes either directly on chorionic villi or on cells cultured from chorionic villi; and (3) isolating fetal cells from maternal circulating blood.

- Respiratory Distress Syndrome (RDS) continues to be a major cause of morbidity and mortality for premature infants. Research includes ultrasonic evaluation of fetal lung maturation as well as studies of hormonal regulation of surfactant apoprotein synthesis in fetal tissues.

- Down syndrome is the most frequently identified cause of mental retardation in the United States. Understanding the basic genetic and biochemical processes associated with Down syndrome is essential. A number of researchers are attempting to understand what genes are located on or controlled by chromosome 21 and to learn about the structure of these genes and the regulation of their expression.

- The mechanisms by which hormones and growth factors stimulate the somatic growth of the fetus are poorly understood. Investigators are using fetal tissue to study intrauterine growth retardation and trying to define the relationships among somatic growth, serum and tissue concentrations of somatomedins, and growth hormone binding.

Question. What is the source of the tissue or cells used for this research?

Answer. The tissue and cells necessary for this research come from human fetal material available as the result of either spontaneous or induced abortion. Under Department of Health and Human Services Regulations for the Protection of Human Subjects of Research (45/CFR/46), federally-funded research involving human fetal tissue must be conducted in compliance with all federal, state, and local law. The Federal regulations include restrictions on tissue procurement that are intended to prevent possible ethical abuses. These regulations state that "Individuals engaged in the activity will have no part in: (i) Any decisions as to the timing, method, and procedures used to terminate the pregnancy; and (ii) determining the viability of the fetus at the termination of the pregnancy." The regulations further state that "No inducements, monetary or otherwise, may be offered to terminate pregnancy for purposes of the activity." This legal separation of the determination of death and the procurement of tissue provides a major safeguard. In addition, the researcher shall have no voice in decisions relating either to the initial determination to terminate a pregnancy, or to the timing or method involved. These decisions rest solely with the patient and obstetrician.

Question. Do you anticipate increasing the level of support for this type of research as a result of the apparent success with neural fetal transplants by researchers in other countries?

Answer. Should experimental fetal tissue transplant procedures be found to be successful, we would anticipate a clear need to conduct additional research on these procedures to assure their safety as well as effectiveness.

Question. What type of review would a research proposal that involved the use of human fetal tissue be given if funded by NICHD?

Answer. The review that a research proposal involving the use of human fetal tissue would be given is the same thorough review that all research involving human subjects is required to pass. This review would include assurances from the Institutional Review Board that such research would be conducted in full compliance with the Federal regulations on such research, as well as in accordance with all state and local law. At each of the four levels of this review process, the reviewers must be satisfied that the research is to be conducted in complete adherence to all protective federal, state, and local laws and regulations.

## PERTUSSIS VACCINE

Question. Over the past few years a new pertussis vaccine was developed by intramural scientists at NICHHD. Subsequently the vaccine was named pertussis toxoid-NICHHD. What has become of the clinical trials scheduled for the vaccine?

Answer. Pertussis vaccine has been tested for safety and immunogenicity in 18 month old infants (80 infants in Goteborg, Sweden, and 100 infants in Boston, Massachusetts). The Swedish infants had never received any pertussis vaccine; the American children had all received their DPT (Diphtheria, Pertussis, and Tetanus) shots at 2, 4, and 6 months of age. In no instance was there any significant adverse reaction, and the vaccine proved to be highly immunogenic.

Trials are now under way in Boston to test three different doses of vaccine in infants at 2, 4, and 6 months of age. The different doses will be given to 30 infants in each case, and then a study of reactions, if any, and antibody production will be assessed. From these data the optimal dose will be determined. An additional 70 children will then receive the selected dose, and the vaccine will be studied for safety and immunogenicity.

Similar studies are planned for Sweden to begin about June 15, 1988, but age groups will be 3, 5, and 12 months, since that is the practice in Sweden. There will be 80 infants in each dose group.

Studies on efficacy are at the planning stage in Massachusetts with the expectation that initiation of the large scale trial will occur in about 12 months. A total of 160,000 infants will be offered an opportunity to participate in the study lasting three years.

In Sweden, efficacy will be tested in 2,500 infants in a program to begin about November 1988. The prevalence of pertussis is so high in Sweden that a double-blind study of the pertussis vaccine is possible with a small number of participants. Nonetheless, we believe testing in the United States is highly desirable and do not believe that the Swedish study diminishes the need to conduct the Massachusetts trial.

## INFANT-MORTALITY-ISSUES

Question. A program entitled Beautiful Babies Right From the Start has been appearing on local District of Columbia television for the past number of years. The project has been an attempt to reduce infant mortality in the D.C. area. Is there any data that would indicate that this program is producing its desired effect?

Answer. The Beautiful Babies Right From the Start program is attempting to increase awareness of the role of prenatal care in the Washington metropolitan broadcasting area serviced by WRC-TV. Broadcasts began about June, 1986 and will continue subject to funding. The joint sponsors include the March of Dimes, Blue Cross/Blue Shield and WRC-TV (channel 4).

Two surveys have been completed to date which indicate an increased awareness of the project in the broadcast area. The program hopes to survey the women served by D.C. Public Health Clinics to measure awareness of the program and use of advertised merchandise coupons.

An NICHD staff member is assisting the sponsors of the project in determining potential methods to measure the effect on awareness of the need for prenatal care and the use of coupons for merchandise provided through Beautiful Babies to encourage better use of prenatal services. Since it is not the only local initiative attempting to improve access or use of prenatal care and ultimately, infant mortality, in the District of Columbia, it will be extremely difficult to ascribe changes in birth weight or infant deaths to the impact of Beautiful Babies Right From the Start.

NICHD is working with another local project, the Better Babies Project, to attempt to decrease the rate of low birth weight in nine census tracts in a high risk area of D.C. through improving access to prenatal care and linkage to social services. The full trial to measure the effects of Better Babies began in September, 1986 and will continue through 1990 to accumulate enough data on the results of pregnancies to evaluate the impact on low birth weight.

Question. Has the infant mortality figure for D.C. improved during the time period that these TV notices have aired?

Answer. The District of Columbia will release its 1987 birth and mortality data in June of 1988. Even when the 1987 data incorporating women who were pregnant during the early airing of the TV notices are available, no direct relationship between the Beautiful Babies Right From the Start and rates of low birth weight or infant mortality can be assumed. The infant mortality rate improved from 24.6 per 1,000 live births in 1980 to 21.0 in 1986. Low birth weight births comprised almost 70% of the infant deaths in D.C. in 1984 (the latest year for which birth and death certificates have been matched to obtain birth weights). The latest available data for infant deaths and the underlying factor of low birth weight are presented below for the District of Columbia:

| | Year | | | | | | |
|---|---|---|---|---|---|---|---|
| | 1986 | 1985 | 1984 | 1983 | 1982 | 1981 | 1980 |
| Infant Death Rate* | 21.0 | 20.7 | 21.2 | 18.2 | 20.3 | 22.6 | 24.6 |
| Percent of Live Births under 2500 grams | 12.2 | 13.2 | 12.8 | 13.1 | 12.0 | 13.0 | 13.4 |
| Percent of Live Births under 1500 grams | 3.2 | 3.3 | 3.2 | 3.2 | 3.0 | 2.8 | 2.7 |

*Deaths per 1,000 live births
Source: District of Columbia Research and Statistics Division

Question. Has infant-mortality in the nation shown improvement in recent years?

Answer. As indicated in the table below, the latest available comparable data for the U.S. show an improvement from 12.6 deaths per 1,000 live births in 1980 to 10.6 in 1985. The percent of low birth weight (under 2500 grams) births has not changed since 1980. The percent of very low birth weight (under 1500 grams) births has increased slightly.

| | Year | | | | | |
|---|---|---|---|---|---|---|
| | 1985 | 1984 | 1983 | 1982 | 1981 | 1980 |
| Infant Death Rate* | 10.6 | 10.8 | 11.2 | 11.5 | 11.9 | 12.6 |
| Percent of Live Births under 2500 grams | 6.75 | 6.72 | 6.82 | 6.75 | 6.81 | 6.84 |
| Percent of Live Births under 1500 grams | 1.21 | 1.19 | 1.19 | 1.18 | 1.16 | 1.15 |

*Deaths per 1,000 live births
Source: Health, United States, 1987, pages 36 and 45.

CONTRACEPTIVES

Question. A year ago it was reported that NICHD researchers were testing a new contraceptive often referred to as RU-486. This form of contraception is also called an abortifacient or sometimes a "morning-after pill." The pill acts to prevent a fertilized egg from implanting itself in a woman's uterus. We may see this form of contraceptive go on sale for use outside of the United States. Will the long-standing debate on the subject of abortion in the U.S. make it virtually impossible for a drug firm to obtain FDA approval for a drug like this? No matter how safe and effective one could prove the drug to be?

Answer. The likelihood that RU-486 would be approved as a method of fertility regulation will depend not only on its safety and efficacy, but also on any legislation that may affect its availability. I cannot estimate the probability of such action.

Question. Will the RU-486 contraceptive ever be available for use in this country in your view?

Answer. As I noted previously, the availability of RU-486 for fertility regulation will be subject to many forces that are impossible to forecast.

Question. Is it true that there are only a dozen grants funded on the infectious theory of arthritis out of hundreds of grants funded?

Answer. The NIAMS awarded seven grants in FY 1987 for $1,248,000 supporting research on infectious agents and arthritis.

Question. How many grants are funded on mycoplasma research?

Answer. In FY 1987 the NIAMS awarded two grants in support of mycoplasma research for approximately $145,000.

Question. What is the total number of grants that have been funded for the NIAMS per year?

Answer. In FY 1987 the NIAMS awarded 593 research project grants.

Question. Is it true that Dr. Barile, of the National Institutes of Health, recently isolated mycoplasma from the synovial fluid of an arthritic and then injected it into a chimpanzee? After a period of time, did the chimpanzee develop Rheumatoid Arthritis? Was the chimpanzee ever treated with antibiotics?

Answer. According to Dr. Barile, he has isolated mycoplasma from an infected joint of an arthritic who was susceptible to superimposed joint infection by having hypogammaglobulinemia (low gamma globulin in blood) and thereby, being immunosuppressed. Dr. Barile injected the mycoplasma into the right knee of the chimpanzee; the chimpanzee developed septic (infected) arthritis in the right knee, but no arthritis in other joints and thus, did not develop rheumatoid arthritis, which is a symmetrical arthritis, involving joints on both sides of the body. The chimpanzee was treated with antibiotics.

## DIRECTOR

Question. Dr. Lawrence Shulman, you were appointed Director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), in January 1987. What has the Institute accomplished since you were appointed?

Answer. Significant progress has been made to date. P.L. 99-158 required a Skin Diseases Interagency Coordinating Committee and an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee be established to better coordinate the research activities and all other aspects of Federal health programs and activities relating to these diseases. These interagency committees have been formed and held their first meetings. The Lupus Erythematosus Coordinating Committee also has been formed, held its first meeting and submitted its report to Congress, which identified numerous avenues for promising research.

I am pleased to inform you that we are nearing the completion of total autonomy from the parent Institute. We are fully operational in the administrative management areas, such as personnel and budget. With our recent recruitments, we soon expect to be fully functional in extramural research, namely, grants management.

Question. What goals have you set for the Institute to achieve within the next year?

Answer. During the next year, we will continue to finalize the complete development of extramural program activities. We have begun to develop our Intramural Research Program Plan. During the past year, we convened an ad hoc research advisory panel of experts to provide recommendations for the future direction of our Intramural Program. We have also laid the groundwork for establishing a new National Plan for the NIAMS. With our advisors, and with the assistance of the extramural research community, we have undertaken a number of workshops and conferences to begin to formulate the future research agenda for the Institute.

## STATUS OF NEW INSTITUTE

Question. At Last year's appropriations hearings you stated that the Institute's overall goal was to fill 36 new positions for the purpose of establishing the core administration of the Institute. Have all 36 positions been filled?

Answer. The 36 positions available last year comprising the major portion of the core administration of the Institute have been filled.

Question. Is there a need to fill additional positions to establish the core of the Institute?

Answer. There is a need to fill the top professional positions of the Deputy Director, NIAMS and the Associate Director for Extramural Programs, NIAMS.

Question. What was the actual cost for setting up the NIAMS?

Answer. The cost to fund the necessary core research, management and support functions of the new Institute is $4.6 million.

Question. How does the actual cost compare with projected cost?

Answer. Projected cost ranged between $3.5 million to $4.5 million.

## PROGRAM DEVELOPMENT

Question. During the 1987 appropriation hearings you mentioned that there were three phases involved in setting up the NIAMS. Have all the phases been completed? If not, then what needs to be done?

Answer. I am pleased to inform you that we are nearing the completion of phase three which is complete autonomy from the parent Institute. We are fully operational in the administrative management areas, such as personnel and budget. We need to recruit the top two positions of Deputy Director, NIAMS, and the Associate Director for Extramural Programs. With our recent recruitments, we soon expect to be fully functional in extramural research activities, namely, grants management.

Question. The NIAMS had a broad mandate to support basic and clinical research in the areas of arthritis and musculoskeletal and skin diseases. What are some of the Institute's research priorities for FY 89?

Answer. Research on rheumatoid arthritis is entering a phase of increased productivity, with many exciting leads for new treatments and improved understanding of current therapies. Several challenges face researchers studying Lyme disease. Researchers supported by the Institute are attacking lupus on a number of fronts. Using techniques of molecular biology, researchers are developing rheumatic disease markers. Such research could lead to tailoring drug treatment more closely to genetic traits and achieving better responses. Attention will be focussed on the diverse manifestations of Sjogren's syndrome.

Osteoporosis will continue to be a major area of research for the NIAMS. Key findings emerged from a scientific workshop on osteoporosis and will be more fully exploited. A workshop was held recently on Paget's disease which served to define advances and provide guidance for future research, both on the pathophysiology of Paget's disease and new approaches to its clinical management. Research approaches for studying osteoarthritis are ripe for exploration and a program announcement will be issued in FY 1988 in collaboration with the National Institute on Aging. The Institute will continue to take active steps to focus the attention of the relevant research communities on musculoskeletal fitness and sports medicine. A Workshop was recently held that placed emphasis on new directions for research on low back pain, and included both a clinical and basic science focus.

In the area of muscle biology, scientists are studying the generation and regulation of muscle tension and relaxation. Researchers are exploring the significance of the recent discovery that one gene contains all the information for the different proteins, or muscles--how this mechanism is controlled and what adaptive advantages it might confer.

The NIAMS supports basic and clinical studies of the skin in both normal and diseased states. Institute-supported research will focus on investigating the skin as an immunologic organ and abnormal immune responses in various skin disorders. This past year it has been discovered that Cyclosporin A is effective in treating psoriasis; this finding is directing research towards immunologic mechanisms in the causation of psoriasis. Because of a new treatment for epidermolysis bullosa, the skin graft technique, future research is expected to generate new information concerning mechanisms of epidermal-dermal adherence, the pathogenesis of blistering diseases, and wound healing.

## NATIONAL ADVISORY COUNCIL

Question. The National Advisory Council had its first meeting in February 1987. What was the outcome of the meeting? Has the Council met again? What was its observations? What was its recommendations?

Answer. The National Arthritis and Musculoskeletal and Skin Diseases Advisory Council provides advice on matters relating to the conduct and support of research training, health information dissemination, and other programs with respect to arthritis and musculoskeletal and skin diseases, including sports-related disorders. In particular, the National Advisory Council reviews applications for grants and cooperative agreements for research and research training and recommends for approval applications for projects which show promise of making valuable scientific contributions. The charter establishing the National Advisory Council was signed by the Secretary, HHS on October 29, 1986, and the first meeting was held February 18-19, 1987. The Council is required by law to meet at least three times each year, and subsequent meetings were held May 20-21, 1987 and September 10-11, 1987. At each meeting, the Council reviewed, discussed, and made recommendations on approximately 300 applications and project proposals. A report on the year's activities and the recommendations of the Advisory Council will be included in the next Biennial Report of the NIH Director, and the Institute will be pleased to make a copy available to the Committee at that time.

Question. You mentioned that the National Advisory Council (NAC) consist of experts from the subspecialities of skin diseases and sports medicine. How many experts from each specialty (including skin diseases and sports medicine) sit on the council? Are there any plans to make additional changes in the composition of the NAC?

Answer. The Advisory Council, like that of the other NIH Institutes, consists 18 members appointed by the Secretary consisting of leading representatives of the health and scientific disciplines relevant to the activities of the Institute and members from the general public, including leaders in fields of public policy, law, health policy, economics, and management. Members serve four year overlapping terms. The Council also has five ex officio members.

At the time the Advisory Council was first appointed, four individuals were transferred from the Advisory Council of the parent Institute. The members were supplemented with 14 additional members whose expertise ranged across the spectrum of the Institute's programs. The expertise of the current members is as follows:

Orthopedic Surgery
Arthritis
Community Programs and Public Policy
Biochemistry and Osteoarthritis
Parent of Arthritis Patient/Community Programs
Orthopedic Surgery and Sports Medicine
Immunology and Rheumatology
Patient with Arthritis/Management
Bone Endocrinology and Osteoporosis
Nurse and Parent of Skin Disease Patient/Public Policy
Health Policy
Muscle Biology
Rheumatology
Dermatology
Orthopedic Surgery
Dermatology
Law/Community Programs
Immunology and Rheumatology

The current members of the Advisory Council have a broad range of specialized and general experience, and is representative of the current need for advice and counsel. As time goes on, as new diseases and research directions develop, the Institute may feel the need for different types of expertise, and the composition of the Advisory Council will change accordingly.

## NATIONAL PLAN

Question. P.L. 99-158 mandates the development of a National Plan for the NIAMS. What steps have been taken to develop a National Plan?

Answer. As required by authorizing legislation, we have laid the groundwork for a NIAMS National Plan. In consultation with advisors, and the extramural research community, numerous conferences and workshops to begin to formulate future research agenda have taken place. Much more remains to be done.

Question. Assuming that this plan is being developed, what needs to be done before the plan can be implemented?

Answer. The plan is still in the evolution stage and needs further development before implementation is possible.

## SPECIALIZED CENTERS OF RESEARCH

Question. In 1987, funding was appropriated for nine new specialized centers of research (SCORS) for the purpose of studying osteoporosis, rheumatoid arthritis and osteoarthritis. Have you awarded any grants to investigators representing each of the nine specialized centers?

Answer. I am pleased to inform you that we received 33 applications for these nine awards. We funded the top three in each of the three high priority areas of rheumatoid arthritis, osteoarthritis, and osteoporosis in FY 1988.

Question. What is the scope of activities of these new centers?

Answer. These nine new centers will focus research resources and efforts basic and clinical research on three diseases of national importance --rheumatoid arthritis, osteoarthritis, and osteoporosis.

Question. How have these centers contributed to the achievement of NIAMS' goals?

Answer. These centers will contribute to the achievement of the NIAMS' goals by allowing for concentrated, coordinated basic and clinical research, which has proven in other fields to be an effective mechanism for the rapid translation of advances in basic science into clinical application and improved health care.

Question. Did the budget request for FY88 meet the anticipated needs of these newly established SCORS?

Answer. The FY 1988 budget level has necessitated a 15-percent downward negotiation in these centers.

Question. During the appropriations hearing last year, you reported that a final review was being planned to evaluate research efforts for the nine new SCORS. Has a research focus been determined for these SCORS?

Answer. The main focus of the new SCORs is in both the basic and clinical aspects of each of the three major disease areas. However, there is a different research thrust in each of these centers that reflects the scientific expertise of the principal investigator and his group, such as immunology, genetics, and endocrinology.

Question. Have any research efforts been evaluated?

Answer. These nine centers have been in existence for less than one year. Therefore it is too early for any evaluation or progress reports.

## SPORTS MEDICINE

Question. At last year's appropriations hearings, you stated that NIAMS was interested in directing some of its resources to research projects in sports medicine. What activity has the NIAMS supported in the area of sports medicine?

Answer. The Institute issued a Program Announcement on Musculoskeletal Fitness and Sports Medicine, to promote additional studies. Several new grant applications have been received in response to this program announcement. The NIAMS also co-sponsored with the American Academy of Orthopedic Surgeons an excellent workshop on Soft Tissue Injury and Repair. In addition, the muscle biology program has an excellent portfolio of research grants.

## INTERAGENCY COORDINATING COMMITTEE

Question. In 1987 you stated the NIAMS was in the process of organizing the interagency coordinating committees. What progress can be reported on the organization of the interagency coordinating committee?

Answer. Section 439 of the Public Health Service Act, as amended by P.L. 99-158, requires the establishment of a Skin Diseases Interagency Coordinating Committee and an Arthritis and Musculoskeletal Diseases Interagency Coordinating Committee to better coordinate the research activities and all other aspects of Federal health programs and activities relating to such diseases. The responsibility for the Committees has been delegated to the National Institute of Arthritis and Musculoskeletal and Skin Diseases, and the Director of the Institute has been designated the Chairman. The Committees are composed of the Directors of each NIH Bureau, Institute, or Division involved in skin-related research, the Chief Medical Director of the Veterans Administration, the Assistant Secretary of Defense for Health Affairs, and representatives of all other Federal agencies whose programs involve responsibilities relevant to skin diseases. The Committees replace similar bodies which met over the past several years. In August 1987, the Institute hired an Executive Secretary for the Coordinating Committees. Letters of invitation were sent to all relevant Federal agencies with a request that they designate a permanent representative to the Committees. The first meetings of both Committees were held in January 1988, and subsequent meetings are scheduled quarterly thereafter.

## OSTEOPOROSIS

Question. Recent reports discuss the progress made in the epidemiology and diagnosis osteoporosis. What research needs to be done to treat osteoporosis?

Answer. A year ago, we held a major Scientific Workshop on Research Directions in Osteoporosis at the NIH to provide a scientific update on current knowledge and research relating to osteoporosis. Specific recommendations for future research efforts were developed, including research on factors that lead to enhanced bone mass in young adulthood and their relation to osteoporosis, and basic research on bone biology and metabolism. Such basic research will lay the groundwork for effective hormonal treatments and other therapies.

Question. Have any breakthroughs occurred in the scientific community to dispel myths, augment treatment or enhance prevention of the condition?

Answer. Among the research advances reported this year, one study clearly confirmed that estrogen replacement therapy by postmenopausal protects against subsequent hip fracture in women. There are also interesting recent nutritional research. Investigators have found that the absorption of calcium from spinach was 5 percent as compared to 28 percent absorption from milk. These findings are important as the American public continues to seek advice on recommended amounts and effective sources of calcium.

Question. Is NIAMS involved in any research designed to investigate prevention of the condition?

Answer. The NIAMS is involved in many basic and clinical research efforts to prevent osteoporosis. Examples include research on hormone replacement therapy, on recommended amounts and effective sources of calcium, and on the many risk factors for osteoporosis.

## ORTHOPEDIC RESEARCH UNIT

Question. The Orthopedic Research Unit was established in 1987. What research projects is the Orthopedic Research Unit currently working on?

Answer. Researchers in this unit study bone biochemistry with a view toward healing fractures, repairing bone deformities, and forming stronger bonds between bone and artificial joint implants. The Orthopedic Research Unit is currently conducting research on bone fracture healing and has developed a model for the study of leg fractures. Scientists are now proceeding to further define the natural history of fracture healing by taking advantage of the new tools of molecular biology of bone. This research may lead to new strategies to speed human bone repair.

Question. How does its research tie in with the overall goal of the NIAMS?

Answer. The studies conducted by this unit are essential to several other NIAMS research areas such as musculoskeletal, bone research and Sports Medicine.

Question. What is the goal of this unit for FY89?

Answer. The unit will expand activities on molecular biology of connective tissues important in bone biology and bone. The

Orthopedic Research Unit will receive additional staff when funds and space become available.

## EPIDERMOLYSIS BULLOSA

Question. The national Patient Registry on epidermolysis bullosa was established in 1987. Describe some of the current activities of this newly established national patient registry.

Answer. Data collection instruments for the newly established EB Registry were approved in May of 1987, and patient enrollment was formally begun at that time. Under the direction of Dr. D. Martin Carter at the Rockefeller University in New York--in conjunction with four EB Clinical Centers located throughout the country--information is being gathered to determine the national incidence and prevalence of EB. Patients are examined, interviewed, and photographed. They are asked to contribute skin biopsy samples and blood specimens for basic research studies, and to allow followup for diagnostic evaluation. Thus far, patient recruitment has exceeded expectations.

Question. To what degree has the registry contributed to the enrollment and classification of patients with epidermolysis?.

Answer. Aimed at identifying the basic defect in EB, improving techniques of diagnosis, and developing effective methods for treatment and prevention, the Registry is already generating comprehensive clinical data on hundreds of patients with EB. Preliminary findings make it clear that many of our clinical concepts related to inherited EB are incorrect. It is now obvious that patients with inherited EB cannot be subclassified accurately simply on the basis of cutaneous features. Whether additional phenotypic variations exist in EB will await final analysis of data, but ultimately we can expect a more accurate definition of both clinical and laboratory features of each of the subsets of inherited EB.

## AIDS

Question. During the justification hearings you reported on the possible relationship between the occurrence of HIV-positivity with rheumatic disease. Would you summarize the current state of knowledge about this possible relationship?

Answer. Investigators from several institutions have reported on the co-occurrence of AIDS and severe Reiter's syndrome, a form of arthritis commonly occuring in young adults. Dual onset of HIV positivity and other forms of arthritis, as well as psoriasis and other skin diseases, has also been documented.

Question. What research contributions might NIAMS make in this area?

Answer. Whether a biological connection exists between certain forms of arthritis or psoriasis and AIDS or whether the co-occurrence of these entities is coincidental will be the subject of future investigations.

Question. Is NIAMS planning any AIDS research (Intramural or Extramural) for FY88 or FY89?

Answer. Intramural scientists at NIAMS are capitalizing on the most current technologies, by combining high resolution electron microscopy with computer image processing, to analyze the structure of the HIV virion. More precise knowledge of the structure of the HIV virion in particular, its glycoprotein envelop will be useful in designing intervention strategies to impede or suppress proliferation of the virus. This research may prove highly useful in vaccine development.

Research will continue into the role of dendritic cells in the skin (Langerhans cells) which may be a target cell for the HIV virus, and partially responsible for immunologic dysfunctions associated with AIDS.

Researchers are pursuing the possibility that an accelerated onset of AIDS may occur in HIV-positive individuals treated with certain immunosuppressive drugs, such as methotrexate. These drugs are currently widely used in the management of rheumatoid arthritis and psoriasis.

The natural history of dermatologic manifestations of persons detected as being HIV positive will be investigated to describe the prevalence and incidence of the full spectrum of skin conditions as they relate to various stages of HIV infection and systemic disease.

## INTRAMURAL RESEARCH PROGRAM

Question. In FY 1987, you said that plans were being developed to separate research endeavors for the intramural research program and to appoint an immunologist to direct that program. Have research endeavors been developed?

Answer. The Intramural Research Program of NIAMS conducts basic and clinical research in the diseases within the mandate of the Institute. These activities include immunology, systemic lupus erythematosus, rheumatoid arthritis, bone research and biophysical studies.

Question. Who is the current director of the Intramural Research Program and what is his background?

Answer. Dr. Henry Metzger, an internationally renowned immunologist, is the Scientific Director of NIAMS Intramural Research Program. Beginning in 1959, Dr. Metzger has had a longstanding research career at the NIH and held various research positions in the Arthritis and Rheumatism Branch of the NIAMS, formerly a part of the NIADDK. He is a world class leader and continues to report excellent scientific investigations. Dr. Metzger holds a A.B. degree from the University of Rochester and an M.D. degree from Columbia University. He served his internship and residency at Columbia-Presbyterian Medical Center in New York. With the exception of a 2-year fellowship in 1961, at the University of California, San Diego, Dr. Metzger's research career has been with the NIH.

## JOINT TRAINING PROGRAM IN RHEUMATOLOGY

Question. A joint training program in pediatric rheumatology was recently established with the Children's Hospital of Washington and the NIAMS. What progress can be reported since this partnership was established?

Answer. A solicitation for applications was advertised in January of 1988 with the intention that the fellow would begin rotation at Children's Hospital in July 1988. At this time a participant has not been selected.

Question. What activities are they planning for FY89?

Answer. A second solicitation will be advertised and efforts to recruit a fellow will continue in FY89.

Question. How much did this partnership cost the NIAMS?

Answer. To date the NIAMS has not made a contribution to this collaborative training program.

Question. How much of the total start-up cost was paid by the Children's Hospital?

Answer. The financial agreement for this program is Children's Hospital of Washington will pay salary costs for the first year of training and the NIAMS will pay salary costs for the second and third years of training. Salary will be commensurate with the stipend for a Staff Fellow at the time of appointment.

Question. How much is the training program expected to cost in FY89?

Answer. In FY1989, The NIAMS will support one trainee with an estimated salary of $25,000.

## BUDGET ISSUES

Question. The Intramural Research Program was authorized a $335,000 increase over that of FY88. Will there be any additional research initiatives in FY89 as a result of this increase in funding? What are some of the Intramural Research Program's priorities for research in FY89?

Answer. The Intramural Research Program will continue to conduct basic and clinical research in the diseases within the mandate of the Institute. These activities include research on muscle tissue, immunology, genetics, systemic lupus erythematosus, bone research, rheumatoid arthritis, and biophysical studies.

## DOWNWARD NEGOTIATIONS

Question. The budget justification states that there will be downward negotiations of 14.6% and 9.3% in the competing and noncompeting grants, respectively. These would appear to be rather significant reductions. In general, what kind of effect will these reductions have on your research programs?

Answer: The downward negotiation of research project grants will limit the scope and slow the rate of progress in arthritis and musculoskeletal and skin disease research.

## INTRAMURAL RESEARCH PROGRAM

Question. Dr. Shulman, what is the status of the orthopaedic intramural research program -- in terms of the type of research to be conducted and the staffing of the program?

Answer. The Institute's Orthopaedic Research Unit conducts bone research and has made significant progress since it's establishment in 1987. Intramural scientists have developed a model for studying leg fractures and are studying the natural history of fracture healing. This research may lead to new strategies to speed human bone repair.

Question. For the record, tell the committee what your future plans are for the orthopaedic research program -- in terms of the type of research to be conducted and the staffing of the program?

Answer. The unit will expand its activities on molecular biology of connective tissues important in bone biology and bone. Additional staff will be added as funds and space become available.

## LOW BACK PAIN

Question. Dr. Shulman, low back pain is associated with enormous suffering and a substantial economic impact. I understand that this is one of the major reasons for workmen's compensation claims. What are your plans for addressing this important research area?

Answer: The Institute is sponsoring its second workshop on low back pain in May 1988. This workshop on New Perspectives in Low Back Pain Research will emphasize new directions for research on low back pain and will include both clinical and basic science deliberatons. Following the Workshop, the Institute will issue a Program Announcement to the research community encouraging additional research on low back pain in areas identified by the scientists at the Workshop.

## OSTEOARTHRITIS

Question. Dr. Shulman, what research advances can you share with us this year on osteoarthritis? I've heard people call this "wear and tear" arthritis - that is to say as we get older the major joints - hip and knee - just wear out.

Answer. The NIAMS sponsored a major workshop in 1985 on the etiopathogenesis (causal factors) of osteoarthritis. Proceedings from that Workshop have been published and provide a course for future research. With this identification of, and focus on, research approaches for studying osteoarthritis that are ripe for exploration, the Institute is issuing a Program Announcement in collaboration with the NIA in FY 1988. The objectives of this Announcement are to encourage studies on pathogenetic mechanisms in osteoarthritis; to promote basic, epidemiologic, and clinical studies; and to foster interdisciplinary investigations.

## SPECIALIZED CENTERS OF RESEARCH

Question. Dr. Shulman, the 1987 appropriations included funds for nine specialized centers of research -- three each in the high-priority areas of rheumatoid arthritis (RA), osteoarthritis (OA), and osteoporosis. Can you bring us up to date on your progress on this initiative?

Answer. The NIAMS received 33 applications in response to our request for applications for the nine specialized centers for research. We funded three excellent centers in each of the research areas of rheumatoid arthritis, osteoarthritis, and osteoporosis. We expect these centers to be an effective means for translating advances in basic science into clinical applications and improved health care in diseases of national significance.

## PHYSICAL FITNESS AND EXERCISE

Question. Doctor, there is a great emphasis in our society on physical fitness and exercising. What role do you see your Institute playing in this area?

Answer. To encourage research in this area, the NIAMS issued a Program Announcement in April 1987 on Musculoskeletal Fitness and Sports Medicine; it seeks to promote studies in basic biology and exercise pathophysiology of the musculoskeletal system. The response to this Announcement is encouraging.

Question. Dr. Shulman, can you tell us about any research activities related to sports medicine this year? Especially as it relates to school age athletes. There seems to be so many young people suffering severe injuries from sports.

Answer. One goal of the Program Announcement issued in April 1987 was to foster epidemiologic studies on sports injuries. The NIAMS has begun to organize a workshop on methods for monitoring causes of athletic injuries in our schools. The objectives of this workshop are to review the current state of knowledge on data collection and analysis for student athletic injuries and to identify methods for developing a system to monitor athletic injuries in schools.

## AIDS

Question. Dr. Shulman, your Institute reported activities related to AIDS for the first time this year. Can you outline for us some of those activities and how do you see research on AIDs as it relates to your Institute?

Answer. Investigators have recently reported the co-occurrence of AIDS and severe Reiter's syndrome, a form of arthritis commonly occuring in young adults. Dual onset of HIV positivity and other forms of arthritis, as well as psoriasis and other skin diseases, has also been documented. Whether a biological connection exists between certain forms of arthritis or psoriasis and AIDS or whether the co-occurrence of these entities is coincidental will be the subject of future investigations. Intramural scientists at NIAMS are capitalizing on the most current technologies, by combining high resolution electron microscopy with computer image processing, to analyze the structure of the HIV virion. More precise knowledge of the structure of the HIV virion in particular, its glycoprotein envelope will be useful in designing intervention strategies to impede or suppress proliferation of the virus. This research may prove highly useful in vaccine development.

Researchers are pursuing the possibility that an accelerated onset of AIDS may occur in HIV-positive individuals treated with certain immunosuppressive drugs, such as methotrexate. These drugs are currently widely used in the management of rheumatoid arthritis and psoriasis.

Research will continue into the role of dendritic cells in the skin (Langerhans cells) which may be a target cell for the HIV virus, and partially responsible for immunologic dysfunctions associated with AIDS.

The natural history of dermatologic manifestations of personnel detected as being HIV positive will be investigated to describe the prevalence and incidence of the full spectrum of skin conditions as they relate to various stages of HIV infection and systemic disease.

## BIOTECHNOLOGY

Question. NIH-supported basic research is a major contributing factor for the current status of the United States as the world leader in biotechnology. NIGMS is a leading participant in this area. More than half of its current budget--$356 million in FY 1987--supports research and training related to biotechnology. In addition, Congress provided NIH with $17.3 million for FY 1988 to support a gene mapping initiative, which is being administered by NIGMS. How are the FY 1988 gene mapping funds being appropriated by your Institute?

Answer. The $17.3 million appropriated in FY 1988 for the gene mapping initiative is being used to support an estimated 76 research project grants, focused on several areas of scientific importance. First, a number of the projects being supported are aimed at improving the research technologies currently available to investigators for doing genomic analysis. More efficient and less expensive methodologies are necessary, in order to make analysis of the large and complex human genome both feasible and practical.

Second, characterization of the genomes of model organisms, such as the C. elegans worm and the mouse, is being pursued in various laboratories. The value of this work is twofold. The techniques devised for constructing genetic and physical maps, and delineating the DNA sequences of such model organisms, should facilitate similar work on complex genomes, such as the human genome. In addition, scientists working on model organisms are learning that significant similarities exist between segments of genetic material in these organisms and in humans. Since, in these models, which have simpler genetic make ups, it is easier to determine specific genetic sequences and delineate their biological functions, results from this research should provide scientists working on the human genome with valuable clues as to the sequence, or possible function of, the parallel segments of the human genome.

Finally, a number of projects funded under the FY 1988 gene mapping initiative are directed toward refining the human genetic map by locating markers--recognizable sites--along the entire stretch of human chromosomes. Having such "sign posts" available at extremely short intervals will facilitate the identification of precise sites on human genes that specify diseases or other instructions of biological importance, such as signals for developmental changes.

Question. What collaborative efforts, if any, are in progress with the National Library of Medicine and your Institute related to biotechnology (e.g., coordination of genetic sequence data banks)?

Answer. Since 1982, the NIGMS has supported GenBank, a computerized data bank that collects, maintains, and distributes information on known nucleic acid sequences. NIGMS also supports the development of computer software, both for small desk-top and large mainframe computers, for DNA and RNA sequence analysis. In the past, NIGMS has supported a protein sequence data bank, the Protein Identification Resource, that is continuing with support from the Division of Research Resources. NIGMS continues to support research to analyze protein sequences. These resources contribute broadly to research in biotechnology, and especially to a major effort to understand how a particular protein sequence leads to a specific folded protein structure with a specific biological activity--a major issue for scientists engaged in biotechnology research as well as basic research.

These efforts have been in an increasingly collaborative mode with the National Library of Medicine (NLM), as a result of the following activities initiated by the NLM:

1. Computer scientists in the Library's Lister Hill Center have developed software that runs on an advanced laboratory computer workstation that allows a researcher to retrieve information simultaneously from multiple biotechnology databases. The researcher may enter a question in his or her own words, and have it answered with information from NIGMS' GenBank, the Protein Identification Resource, the Library's own MEDLINE database, and/or other information sources.

2. NLM has mapped keywords in GenBank to corresponding terms in Medical Subject Headings (MeSH), NLM's 15,000-term vocabulary used in indexing millions of journal articles. MeSH itself has been expanded with new index terms for papers that report protein and nucleic acid sequences as well as other biotechnology data.

3. The Library is building a "database of biotechnology databases" that will help scientists locate not only molecular biology information, but also such resources as tissue banks, bacteriological strain libraries, clone libraries, and enzyme databanks. This directory of databases will be available as an on-line service and as diskettes that can be searched with a desk-top personal computer.

4. NIGMS and the NLM are also cooperating in information handling and data management required for the recently initiated Human Genome Initiative.

Informally, NIGMS and NLM personnel maintain close contacts, particularly with respect to GenBank. Computer scientists at the Lister Hill Center have provided important technical advice with respect to the computational aspects of the project. Monitoring of progress on the GenBank contract is facilitated by software and computer facilities provided by NLM. On the other hand, NIGMS personnel have provided important advice regarding the biological aspects of activities in biotechnology initiated by the Library. This partnership, which takes advantage of complementary expertise, has worked for the benefit of all.

It is noted that the NLM has contributed funds to the support of GenBank.

## MOVEMENT OF SCIENTISTS TO BIOTECHNOLOGY FIRMS

Question. What information do you have on the attrition rate, for scientists who have been supported by NIH research trainee programs and/or research projects that would support biotechnology, from the academic or NIH-intramural research environment into the industrial sector?

Answer. To date, there has not been a comprehensive manpower analysis of the mobility of scientists among and between the universities, the biotechnology industrial sector, and the NIH intramural program. However, non-quantitative assessments clearly show a substantial rate of employment of both university-based and NIH intramural scientists by biotechnology firms. For the university sector, the current rate of attrition (estimated as from 7 to 12%) into the industrial sector will be elevated to crisis levels in several years, owing to a projected 40-65% retirement rate for an aging population of university scientists.

## AIDS

Question. NIGMS administers a program initiated by NIH in 1987 and aimed at studying the structure and biology of the AIDS virus. This program currently supports six research teams who received 5-year awards (which totalled $5 million for the first year) that are attempting to make drugs to treat AIDS. What progress has been made in finding a treatment for AIDS?

Answer. The purpose of this program is to develop a targeted strategy for drug design to combat AIDS. This is a novel approach, which starts with a detailed knowledge of the structure of proteins presumed to be involved in the disease process. The investigators then attempt to "tailor" drugs which are designed to specifically bind to any of these proteins and modify their behavior. The research teams funded by this program are attempting a coordinated effort in which the structure of AIDS-related proteins are determined, while at the same time approaches are being developed for drug design. After nine months, a number of proteins have already been purified, and structure determinations are underway. These initial stages of the projects are proceeding well. Over the next several years, a good deal of additional work will be needed to move closer to delineating effective treatments for AIDS.

Question. Do you anticipate increasing your support in this area to other research teams?

Answer. At the moment, we are only funding the six existing groups. However, we attempt to incorporate other appropriate programs, both through collaborations and by providing supplemental funding to the program projects when needed.

Question. How are you collaborating with other institutes in this area?

Answer. We maintain very close contact with the National Collaborative Drug Design programs of the NIAID. A number of investigators are involved in both the NIGMS and NIAID programs. We also collaborate closely with the structure and drug design effort of the intramural program of NIH. A meeting of investigators working in this area was held in November 1987, and included participants supported by NIGMS, NIAID, and the NIH intramural program. A second meeting, to be held in June 1988, is expected to have even broader participation.

## TRAINING

Question. NIGMS is a major participant in supporting training programs targeted at selected groups, e.g., physicians, minorities. How is your Institute addressing the problem of underrepresentation in scientific fields by minorities?

Answer. Since 1975, the NIGMS has operated the Minority Access to Research Careers (MARC) Program, which provides special research training opportunities in the biomedical sciences in order to attract minority students to research careers. The largest component of this program, the Honors Undergraduate Research Training program, helps prepare outstanding science majors for graduate study in the biomedical sciences. About 80 percent of the graduates of this program have gone on to either graduate or professional schools. The other components of the MARC Program help minorities pursue graduate or advanced study in the biomedical sciences. All of these efforts are aimed at increasing the representation of minorities pursuing careers in the biological sciences.

Question. Do you anticipate expanding your support to include programs to include high school students?

Answer. Because the Division of Research Resources, NIH, operates the Minority High School Student Research Apprentice Program, NIGMS believes that further expansion of its Minority Access to Research Careers (MARC) Program to include high school students would be a duplicative effort. Most of the institutions at which there are MARC research training programs are among the approximately 270 research institutions that participate in the DRR program. That program currently supports 1,000 high school students for an eight week summer experience working in research laboratories. This "hands on" laboratory experience is intended to heighten the interest of the participating minority students in pursuing college careers in the biological sciences.

## Toxic Substances and Human Health

Question. Possible threats to public and occupational safety and health by exposure to myriad substances always exist. While it is a goal of this Institute to conduct health research in a non-crisis manner, nontheless it is a fact that events sometime force a sudden focus on a specific potential insult to health, e.g., ethylene dibromide in the food supply some years ago, or methyl isocynate and the explosion in Bhopal, India in 1984. How does NIEHS plan to allocate its resources between non-crisis and emergency research?

Answer. Research findings from over 20 years of studies conducted and supported by NIEHS are available to Public Health and Environmental Protection Agency personnel for use in emergency situations. For example, studies of the health effects of dioxin were done at NIEHS in the early 1970's, well before it was found in soil at Times Beach, Missouri prompting the emergency evacuation of the town. Data from NIEHS dioxin research were used as the basis for clinical and epidemiologic studies of Times Beach residents.

There are emergency situations which require NIEHS to provide immediate assistance. The catastrophe of Bhopal was such a case. In that instance an NIEHS scientist went to Bhopal as a part of the US medical response team to evaluate the conditions and to make recommendations for toxicologic studies of the long-term, chronic effects which might be expected to result from the acute exposure.

The NIEHS university-based Environmental Health Sciences Centers also provide a resource to assist in environmental emergencies. The director of the NIEHS Center at Johns-Hopkins went to Bhopal as a member of the US team to offer clinical advice in the care and treatment of survivors. This year NIEHS expanded the clinical and epidemiologic assessment services available through the Centers for the evaluation of clusters of illnesses which may be related to occupational exposures to environmental hazards. This new effort is coordinated with the National Institute for Occupational Safety and Health.

Question. How do you plan to avoid "robbing Peter to pay Paul"?

Answer. In the event of the need for environmental emergency responses, NIEHS usually provides scientific advice and support based on our understanding of the environmental health sciences. For most of the scientific advice provided by NIEHS, the NIH financial management system is sufficiently flexible to allow modest sums to be transferred so as to accommodate the situation with proper justification.

In the event of major environmental emergencies, monies are available from the Comprehensive Environmental Response, Compensation, and Liability Act--Superfund Program--Trust Fund to support the costs of NIEHS work. In some cases, supplemental funds have been requested. The exposure and uptake of dioxin from soil from Times Beach is an example.

Question. How does NIEHS set its research priorities and rank the thousands of substances that could or should be tested?

Answer. NIEHS has procedures for setting research priorities which take into account the needs of the Federal environmental, occupational, and consumer protection agencies as well as the general need to expand the base of knowledge of the toxicity of widely used chemicals. These agencies, other individuals or organizations nominate compounds for toxicologic testing. These compounds are reviewed by NIEHS scientists for potential toxicity, the extent and kinds of use, and the potential for wide-spread exposure to people. Before a compound is studied by NIEHS, all the known toxicologic data are evaluated, efforts are taken to assure that the compound is not being studied by another agency or by industry and the protocol for the study is peer reviewed. This system avoids unnecessary duplication, meets urgent regulatory and other public health protection goals, and offers opportunities for public and scientific participation in the NIEHS research plan.

## Interagency Coordination of Occupational Safety and Health Programs

Question. The protection of public and occupational safety and health are the goals of many Federal entities, including NIEHS, the Environmental Protection Agency (EPA), and the Occupational Safety and Health

Administration to name just three. How are research and research priorities coordinated among all the agencies concerned with health?

Answer. The coordination of research and research priorities is excellent both within the Public Health Service agencies and between the PHS and other Federal agencies. An outstanding example of this coordination can be found in the structure of the National Toxicology Program (NTP) which was chartered by the Secretary to coordinate toxicologic research among each agency of the Public Health Service. NTP is directed and managed by the Director of NIEHS. Its Executive committee is made up of the directors of agencies with toxicologic programs. Substances which are nominated for test by NTP must pass through a process of review which includes advice from scientists for their agencies. Additional input and coordination is available from liaison members to NTP committees from other agencies. For other research conducted and supported by NIEHS the Health Research Extension Act of 1985, P.L. 99-158, Sec. 406, calls for an Advisory Council to review our research, grants and contracts. We have added liason members from FDA, CDC, NIOSH, ATSDR, and EPA to this council. The Department also started a Committee to Coordinate Environmental Health and Related Programs (CCEHRP). Each major operating component in the PHS with an environmental health program is a member. The EPA has a liaison member. This committee has a standing sub-committee on research priorities and needs.

At NIEHS, we coordinate our Superfund Basic Research and Training Grant Program with EPA and ATSDR through the legally mandated Advisory Council and through quarterly meetings with EPA and ATSDR.

A staff scientist from NIEHS serves as the Chair of the Interagency Testing Committee established by the EPA under the Toxic Substances Control Act.

## National Human Monitoring Program

Question. The National Human Monitoring Program (NHMP) was started in 1967 with the purpose of monitoring human exposure to pesticides. Its usefulness grew as other toxic, nonpesticidal, substances were added to the list of monitored chemicals. The usefulness of the Program is in knowing what chemicals people in different geographic regions have been exposed to, and how effective exposure reduction programs have been, with the goal of reducing human exposure to toxic chemicals. The NHMP began with the National Human Adipose Tissue Survey (NHATS), to identify chemicals which accumulate in human fat. Because not all chemicals accumulate in human fat, NHMP was to include the National Blood Network (NBN) to identify chemicals which accumulate in blood; a pilot study of the NBN was to have begun in FY88. Late in 1987 EPA proposed to terminate the NHMP in 1988 as a money saving measure the FY87 EPA budget for the NHMP was about $1 million. In March 1988 EPA announced a new decision to spend in the current fiscal year $750,000 on the NHATS, to not proceed with the NBN, and to spend $150,000 on a National Academy of Sciences evaluation of the NHMP. The agency has proposed spending $900,000 on the NHATS in FY 89. Data from the NHMP have been used by researchers in other EPA programs, in other Federal agencies, and in private research organizations. Has NIEHS used data from EPA's NHMP?

Answer. Yes. Mostly for information on the trends of pesticide exposure and uptake in people over time.

Question. If so, how would NIEHS secure the kind of data contained in the NHMP, if EPA terminated the program?

Answer. Although there are many clinical and epidemiologic study uses for the kinds of data contained in or available from the National Human Monitoring Program, the utility of these data to the basic research studies produced or supported by NIEHS is limited. In these instances where a scientist from NIEHS or an NIEHS grantee needed data such as those available through the NHMP, and the NHMP were terminated by EPA, we know of no other source.

Question. Has NIEHS worked with EPA to prevent the termination of the NHMP?

Answer. We have contacted EPA to suggest that NIEHS would be willing to discuss alternatives to its termination.

Question. Is such work being considered?

Answer. Because of concerns voiced by others about their decision, EPA decided not to terminate the NHMP and further discussions between NIEHS and EPA on the matter were not necessary.

## Research Management Issues

Question. The criticism has been heard that some scientists, sometimes moved into management for having performed good research, cannot efficiently or effectively manage research. What procedures or training programs exist to insure that NIEHS managers can efficiently and effectively manage research?

Answer. All of the Institutes' Division Directors have had considerable management training at the Federal Executive Institute, the Brookings Institute, or at special university management training seminars. Lower level managers receive on-site and Office of Personnel Management courses in topics such as project management, supervision, EEO, and contracts management.

Question. What procedures exist regularly to evaluate and re-train, as needed, NIEHS managers for efficient and effective management?

Answer. All managers, SES and general schedule, are rated annually on their management skills as part of their overall evaluation. When deficiencies are noted specific courses are scheduled. In addition, seminars and courses are given whenever new policies or procedures affecting management are issued.

Question. Has NIEHS conducted studies, and have plans been made, to decrease the administrative costs of the institute, without adversely affecting its operations?

Answer. NIEHS has had an active Productivity Committee in place for several years. It has eight sub-committees and involves personnel from the laboratories and offices as well as representatives from the various management and resource support areas. This ongoing committee continually reviews administrative activities such as procurement and engineering and makes recommendations on efficiency, cost and effectiveness.

## Salary Competition From the Private Sector

Question. Concern has been expressed that NIH and NIEHS may be in danger of losing preeminence. There are several reasons given for the concern, including; limitations on salaries, number of personnel, opportunities for participating in International meetings, and facilities and space; and increased competition from other research centers--some public, some private, some foreign. Have you experienced difficulty attracting or retaining competent, respected, and productive scientists, engineers, and other professional staff?

Answer. Yes, particularly during the last few years.

Question. Why?

Answer. Primarily because of the higher salary that the private sector pays. For example, seven scientists who have left the Institute for the private sector during the past few years have received an average salary increase of 53%. The range has been from a low of plus 26% to a high of plus 83%. More generous policies in the private sector on travel, outside activities and other non-scientific issues also plays a part.

Question. Is there presently a problem, or do you project a problem, with the ratio of foreign to American scientists and professional staff?

Answer. No. We have had a fair number of visiting fellows in the past, but these are short term non-tenured positions. We are reducing that number and increasing US fellows through the Intramural Research Training Associate Program.

Question. Is there presently a problem, or do you project a problem, with the number of minority American scientists and professional staff?

Answer. Yes, this continues to be a problem. There are relatively few minority scientists entering the job pool each year and the competition from private industry and academia with their higher salaries is very stiff.

Question. If so, what actions are occuring or planned to alleviate these problems?

Answer. Several efforts are currently underway. NIH is supporting the training of more minority students, teachers and scientists with an eye toward interesting them at an early stage in their science careers. Other efforts include increasing grants to minority institutions, more fellowships and training grants, and attempts to raise salaries for fellows and other junior scientist positions.

Question. Has NIEHS explored jointly funding environmental health research with private sector firms or other governments and the implications of such funding?

Answer. Historically, the NIEHS has entered into numerous collaborative and jointly funded research endeavors with both public and private organizations. This is especially true in our relationships with the outstanding major research institutions located in the Research Triangle Park area. These jointly funded activities involve a full range of support on the part of both the NIEHS and collaborating institutions, from funding of research and technical support personnel to the provision of space, instrumentation and supplies.

Question. If so, what are your conclusions?

Answer. These collaborations have made it possible for NIEHS investigators to extend their research capabilities significantly by taking advantage of local research facilities, equipment and manpower resources generally not available within the NIEHS. Examples of on-going or recently concluded efforts include: a Protein Laboratory for Collaborative Research in the Department of Chemistry, University of North Carolina provides both the NIEHS and UNC investigators access to automated instrumentation for solid-phase synthesis, purification, amino acid analysis, and microsequencing of peptides and proteins; for over five years a specially built avian research facility in the Department of Poultry Science, North Carolina State University provided housing and maintenance services for care of Japanese Quail, and provided research and technical support staff for collaborative biological studies on birds exposed to environmental agents; NIEHS National Toxicology Program (NTP) investigators, in collaboration with investigators at the Duke University School of Medicine, use Duke facilities for Magnetic Resonance Imaging to study the programs of natural and chemically induced adverse lesions in rats; investigators of the Laboratory of Cellular and Molecular Pharmacology, NIEHS, utilitize facilities of the Duke University Marine Laboratory in Beaufort, N.C. on an intermittant basis for ready access to aquatic species used as models in environnmental studies on mechanisms of xenobiotic excretion; NTP investigators are engaged in a jointly funded collaborative rat and mouse cell turn-over study with the Chemical Industry Institute of Toxicology here in the RTP and the Battelle Northwest Laboratories in the state of Washington.

Question. What are your views on increased competition from other research centers--is such increased competition good or bad for research, or ultimately good or bad for the protection of environmental health?

Answer. I think it is good. Science is based on competition and replication, one lab building on the results of another. We must be careful that the competition for scientists doesn't lead to the concentration of science in a few large labs, and that commercial applications don't overwhelm more basic scientific issues, but in general it is good for the public health.

## Air Pollution and Hospital Admissions

Question. A reviewed study of hospital admissions and air pollution importantly notes that "...the postulate that ozone and SO4...acting as surrogates for some much more damaging (chemical) species that is not routinely monitored would be consistent with our data..." Please describe NIEHS' activities with regard to identifying and ranking by degree of hazard the myriad outdoor air pollutants.

Answer. NIEHS has been deeply involved in conducting and supporting basic research into the health effects of environmental pollutants found in outdoor air in the United States. One principal research focus has been to develop biologically relevant monitoring systems. That is, to work toward the development of systems that correlate the existence of air pollution at various levels, with adverse health effects in people living in areas where air pollution occurs. The Harvard Six City Survey which compares health effects in the lungs of children in areas with high levels of pollution with effects in children in areas with clean air has helped EPA determine strategies to control priority pollutants and to include standards and guidelines on the basis of their human health protectiveness and biologic relevance. This basic epidemiologic research was supported by NIEHS, and implemented a number of years ago in a forward looking attempt to identify and rank outdoor air hazards. We have also conducted and supported basic research into the health effects of lead. The results were used by EPA to set standards for this toxic compound. We share the concern about the potential effects on human health resulting from exposure to ozone in the ambient air. We have increased our studies of the toxicology of ozone to help efforts to better clarify and quantify its hazards.

The selection of additional priority pollutants and other air pollutants of concern to human health is made by EPA in part on the basis of toxicologic studies conducted or supported by NIEHS. The effects on the lung from the acids in the mists in areas affected by acid precipitation is another NIEHS research priority.

Question. How are your fundings incorporated into EPA air pollution control strategies?

Answer. When the results of research conducted or supported by NIEHS indicate that a chemical has the potential to damage human health, these findings are made available to EPA. The ofice in EPA which analyses these data and makes recommendation for strategies to protect human health is located in Durham, North Carolina, only a few miles away from NIEHS. Thus, the opportunity for interactions between NIEHS staff and the EPA at the scientific level in this work are particularly good. The interaction between NIEHS and EPA scientists in the EPA efforts to develop a standard for lead in ambient air were strong.

The strategies to control air pollution must take into account many factors besides the toxicologic study results or the results of epidemiologic studies such as the Six City Study conducted by researchers at Harvard and supported by the NIEHS. Standard setting, engineering controls, environmental assessment, and enforcement actions are appropriately the responsibility of the EPA. The role of NIEHS is appropriately limited to providing sound data from basic environmental health sciences research.

Question. Are you satisfied with the way EPA does or does not use your findings?

Answer. It has been our experience that EPA has reviewed all of the research studies conducted or supported by NIEHS related to those substances that are known to be air pollutants. These EPA reviews and analyses accurately interpret the findings of the NIEHS research and these findings often appear to have influenced those regulatory decisions made by EPA.

## Indoor Air Pollution

Question. It has been reported that indoor air pollutants can and often do vary significantly from outdoor pollutants in concentration and type. Research and regulations to protect health from air pollutants traditionally have focused outdoors, despite the fact that most people spend the vast majority of their time, up to 90 percent, indoors. Concerns have been expressed that the current standards for some air pollutants are not adequately protective of health. Please describe NIEHS' activities with regard to identifying and ranking by degree of hazard indoor and outdoor air pollutants.

Answer. Last month NIEHS sponsored a conference "Environmental Health in the 21st Century",to which we invited a group of distinguished scientists to predict toxicologic advances we can expect to take place in the next century, and to help identify any possible adverse environmental health impacts. At this conference, Dr. Jan Stolwijk of Yale University presented a facinating overview of the problems of indoor air pollution and suggested that the problem may become even more troublesome. Data on indoor air quality from both the U.S. and Europe generally confirm that concentrations of contamination are generally significantly higher indoors than outdoors. Dr. Stolwijk's analysis of the data shows that the resulting hazards from common, ubiquitous compounds such as benzene and toluene must be viewed with concern by public health officials.

While NIEHS basic research into the health effects and toxicity of chemicals commonly found in indoor air has provided the basis for many of the proposed hazards in residential and office air, much more research is needed. The conditions present in residences are quite different from those in industrial settings. The occupants of residences spend more time at home than workers spend in industrial plants, and the residents are often more vulnerable because they are young or infirm, rather than healthy adult workers. We are embarking on an expanded program of research into the health effects of indoor air problems. This year we are studying the effects of radon in residential settings. We will continue to work with EPA and other agencies to review the findings of monitoring and surveillance programs and to provide a sound science basis for strategies to protect human health.

Question. Do your findings suggest that current standards for some air pollutants are not adequately protective of health?

Answer. The findings of some of the research studies conducted or supported by NIEHS taken by themselves could suggest that some existing standards for priority air pollutants in the outdoor environment may not be fully protective of human health, particularly in persons with certain pulmonary diseases.

Question. Do your findings suggest that there may be need to consider hazard control strategies for certain indoor air pollutants?

Answer. There is a growing body of scientific evidence, part of which comes from NIEHS work, that the indoor air environment can have a serious adverse impact on human health.

Question. If so, which pollutants, and what sorts of strategies?

Answer. The "tightening" of homes, apartments, and office buildings to make them more energy efficient has had the effect of trapping hazards such as particulate matter, smoke from tobacco and wood fires, fumes and exhausts including such compounds as oxides of nitrogen from furnaces and gas stoves, and chemicals in household products. These hazards must be made known through public education and awareness programs and susceptible individuals such as children and the chronically ill should take precautions to avoid or reduce exposure. The most appropriate strategies for the protection of public health from indoor air hazards in residential settings involve education and advisories based on sound scientific study.

By now, almost everyone is aware that houses built over certain naturally-occuring rock formations can trap and accumulate radon gas. Radon is a health hazard, but most of the information about its effects in humans comes from studies of uranium miners. The extrapolation of data from these studies to the typical residential setting is difficult. More and better research is needed to determine the actual hazards from various radon levels in residential settings. NIEHS is involved in this research.

Question. How is NIEHS coordinating with other agencies, like EPA?

Answer. NIEHS participates in the meetings of standing interagency committees and monitors the activities of ad hoc task forces and working groups.

## Research Costs

Question. Concern about the rising costs of research interacts with concern about the proper care and use of animals in research. Please describe the procedures by which NIEHS insures that animals are properly cared for and used in research.

Answer. NIEHS has given high priority to marshalling its available resources to insure proper animal care is maintained at all times. An indication of our effectiveness was the certification from the American Association for the Accreditation of Laboratory Animal Care which was received in October 1987. This independent body of reviewers, not affiliated with the government, found no deficiencies and in a rare adulation, commended NIEHS for an outstanding animal care and use program.

Internally, the Institute has the Animal Care and Use Committee which reviews and approves every animal study for proper and humane procedures prior to the initiation of a study. The committee is, under PHS Policy, the single most important aspect of animal welfare oversight. The group is composed of senior NIEHS research staff, all with extensive animal experience, the Institute's Senior Veterinarian as well as a representative from the community. In addition, NIEHS has filed and continues to update its statement filed with the NIH Office of Protection from Research Risks, an office established by NIH to administer the Public Health Service's Animal Welfare Policies.

Training is an important integral part of NIEHS animal care development. It should be noted that a mandatory investigator training course must be completed before any research project is initiated at NIEHS. This ensures that researchers are familiar with animal welfare policies and principles and that alternative methods have been explored before studies are begun.

The average NIEHS employee involved in direct animal care activities has a bachelor's degree in animal science or biology as well as an additional level of certification by the American Association for Laboratory Animal Science. Each animal care employee has a personalized training plan spanning several years and periodic workshops are held for animal care personnel to update and upgrade knowledge, skills, and techniques.

Question. What research is NIEHS conducting on the development and validation of toxicity tests which don't rely on animals?

Answer. NIEHS research includes a range of approaches aimed at better understanding the nature and mechanism of action of factors that affect human health. Our scientists are continually seeking more precise and less expensive ways to develop this information. This orientation is central to their scientific investigation and is complemented by the desire to decrease the numbers of animals used in research.

Scientists at NIEHS have investigated and continue to investigate a number of short-term toxicological assays that do not require whole animals. The assays are designed to help predict which chemicals may be hazardous. These provide very specific information about mechanisms of cellular damage and identify and characterize chemicals that cause toxicity. Among examples of these systems are tissue culture systems to study a multistep model of carcinogenesis, in vitro screening systems for teratogens, cell culture system for study of toxic effects in the kidney, continued development work on the Salmonella mutagenesis assay, and a human cell assay for genetic toxicity. Other important non-animal work includes computer modeling of initial events in carcinogenesis, sophisticated research instrumentation for chemical analysis, and exquisitely detailed study of injury at the cellular and molecular level using bacterial strains.

In addition, there are also a wide range of approaches under development by NIEHS that contribute directly and indirectly to the use of fewer animals. These include improvements in toxicological study design, investigation of the disposition of chemicals in biological systems, and refinement of magnetic resonance imaging techniques. Screening approaches have been developed that provide an indication of the need for longer term study. NIEHS, for example, has in place a testing rationale that involves the execution and evaluation of certain prechronic test results prior to making a decision to carry out a two-year animal study.

The utility of any new system is first dependent upon confidence that it is measuring what it was intended to measure and that it is reproducible among laboratories. Validation of a non-animal method requires, among other things, meticulous evaluation of the consistency between the results in the proposed system and the results from whole animal studies. The validation process is complex, involves many years of research, and is very costly.

Since Bruce Ames first developed his mutagenicity assay, it has taken years to fully evaluate its predictive utility for carcinogenicity and to validate it completely. We have learned that a positive in vitro mutagenicity test result is a clear signal that a chemical is likely carcinogenic in laboratory animals, however, a negative mutagenicity result is ambiguous regarding mammalian carcinogens. NIEHS will continue to direct research aimed at the development and validation of systems that do not utilize animals, but I am afraid it will be some time before they will, in any comprehensive fashion, replace whole animal models.

## Spread of AIDS

Question. Are NIEHS resources being spent to screen potential or current employees for AIDS?

Answer. We are not currently testing employees or applicants for AIDS.

Question. Are NIEHS resources being spent to hire and employ persons who test positive?

Answer. As I said, we do not test anyone at this time.

# QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

## BUDGET REQUEST

Question. What was the Original Request to the NIH Budget Office?

Answer. The NIDDK requested $697,037,000.

Question. What was the Department's original request to the OMB?

Answer. The Department's original request to the OMB for NIDDK was $487,042,000.

## FULL TIME EQUIVALENTS

Question. What was the original FTE request to the NIH Budget Office?

Answer. Our original budget request included 643 FTEs; 460 for intramural research and 183 for research management and support.

Question. How does this compare to the FTE allocation in the President's Budget?

Answer. The current budget request provides for 573 FTEs.

## CYSTIC FIBROSIS CENTERS

Question. Dr. Gorden, last year this Committee was supportive of the creation of Cystic Fibrosis Centers. Will any centers be created in 1988?

Answer. The 1988 Appropriation calls for the establishment of new Cystic Fibrosis Centers. To date no awards have been made, but 2 or 3 will be made before September.

Question. If so, how much money will be spent on the centers?

Answer. The 1988 Appropriation includes earmarked funds of $2,394,000 for the establishment of new Cystic Fibrosis Centers. In addition, the existing center at Case Western Reserve University will receive about $976,000 in FY 1988.

Question. If no, how much more money would be needed in FY 1989 to establish a center?

Answer. We estimate that an appropriate average level of funding for a Cystic Fibrosis Center would be between $850,000 and $1,000,000.

## INTERSTITIAL CYSTITIS

Question. Dr. Gorden, as you know, this Committee has encouraged increased research for the painful and debilitating condition of Interstitial Cystitis. Will you be able to increase research activities in this area in FY 89? If not, what additional resources would be needed to solicit research proposals on the etiology and treatment of interstitial cystitis.

Answer. No sir, we will not be able to set aside additional special funds for this area in FY 89. We believe that it would require additional support for approximately 10-15 new awards. This would require approximately $1.5 to $2.5 million. However, if we receive investigator initiated grant applications in this area which compete well in our peer review process, we will of course fund those that fall within our payline.

## DIGESTIVE DISEASES

Question. Dr. Gorden, I understand diseases of the digestive tract are the leading cause of hospitalization and major surgery in the U.S. What kind of research is NIDDK conducting that might result in a decrease in hospitalization and treatments that would preclude the need for surgery?

Answer. An Institute supported grantee is conducting a trial of endoscopic hemostasis in ulcer hemorrhage. If endoscopic hemostasis proves as effective as predicted, it will offer a substantially less costly and less traumatic alternative to the traditional surgery and hospitalization that is now required for some patients of bleeding ulcer.

Another grantee is conducting studies of the use of the endoscopic echo probe to investigate the level and extent of a disease process involving the intestinal wall. This research offers the possibility of a remarkably less costly and traumatic alternative to exploratory surgery to diagnose intestinal disease.

The new experimental method by which cholesterol gallbladder stones are being dissolved using methyl tert-butyl ether (MBTE) may provide some cost savings over conventional cholecystectomy. However, its great virtue at the present time is that it can be a life-saving measure in patients who are at extremely high risks for surgery. This is the group of patients upon whom the procedure is currently being tested. Potentially, if the experience on this group of patients continues to be good, then the procedure may be used on others. The patient needs to be in the hospital only two or three days, but because of the need for intensive medical supervision, the costs may be about equal to the cost of a cholecystectomy in which hospitalization may be about seven days. The cost savings occur in the more rapid return to gainful employment. The MBTE patient can return to work within a week; the cholecystectomy patient in three or four weeks.

Another experimental method of removing gallstones without surgery which may eventuate in reduced cost, especially time lost from work, is that of extracorporeal shock-wave fragmentation of gallstones (lithotripsy). After the European experience in which this nonsurgical procedure was used to treat 175 patients with cholesterol gallstones, a controlled, 10-center clinical trial is being initiated in the United States to assure safety as well as efficacy. The lithotripsy is combined with medical therapy (ursodeoxycholic acid) to dissolve the small fragments of gallstone left from the shock-waves. The cost of the specialized lithotriptor needed for the procedure is high, but there is the potential for considerable savings in hospital stays and periods lost from work.

## BUDGET REQUEST

Question. What was your original budget request to the NIH Budget Office?

Answer. The original request to the NIH Budget Office was $652,354,000 excluding $13,393,000 for AIDS research.

Question. What was the Department's request to the OMB?

Answer. The original NINCDS request to OMB was $468,753,000 excluding AIDS.

## FTE's

Question. What was your original FTE request to the NIH Budget Office?

Answer. The original FTE request to the NIH Budget Office was for 728 FTE's.

Question. How does that compare with the allocation in the President's Budget?

Answer. The President's Budget includes a request for 676 FTE's, equal to the FY 1988 FTE strength.

## NIMH/NINCDS

Question. Dr. Goldstein, at my request, this Committee asked the Director of the National Institute on Mental Health and the Director of the National Institute on Neurological and Communicative Disorders to report on coordination of Research in the Neurosciences and Mental Disorders. The report, which was forwarded to the Committee in February, made 4 specific recommendations:

- Enhance the current research training programs of the NIMH and NINCDS and the coordination of NIMH and NINCDS programs of basic and clinical neuroscience research training to address the biomedical issue of neurological and mental disorders, including schizophrenia;
- Initiate regularly scheduled meetings of the Directors of NIMH and NINCDS to increase the coordination of future research and research training activites;
- Officially designate a liaison member from each Institute to the other Institute's National Advisory Council; and
- Increase the human brain banking facilities which are co-funded by the NINCDS and the NIMH.

I am particularly interested in the recommendation to enhance and coordinate research training programs. Can you tell me how this recommendation will be implemented and how much has been requested for such training the the FY 89 budget request?

Answer. The two Institutes will be jointly examining research opportunities with a special emphasis on areas where training programs specific to the mission and scientific competence of each Institute may be supported by the Institutes. These will include areas of interest of the two Institutes related to various neurological and mental disorders. Appropriate applications for such training will then be solicited from the research community. The scientific areas involved will be identified through two concurrent activities. The first is the regular, on-going meetings between the Directors of NINCDS and NIMH, an activity that has already been initiated. The second, which will be initiated in May 1988, is the exchange of liaison members from the National Advisory Councils of the two Institutes. The resulting interchange of ideas and discussion of scientific areas of mutual interest is expected to provide the basis for coordinated efforts in research and training. The 1989 budget request for research training for the NINCDS is $14,210,000.

## TRAUMATIC BRAIN INJURY

Question. Dr. Goldstein, I have long been concerned about the need for research and rehabilitation services related to traumatic brain injury. Recently, the Senate Subcommittee on the Handicapped held a hearing which focused on traumatic brain injury and the need for more basic and rehabilitation research in this area. Dr. Goldstein, how much of your budget is devoted to rehabilitation research for survivors of traumatic brain injury?

Answer. The vast majority of rehabilitation research and rehabilitation services for survivors of traumatic brain injury is supported by the National Institute on Disability and Rehabilitation Research (DOE). The NINCDS does, however, sponsor some rehabilitation-related research as components of some of its head injury projects. It is estimated that the NINCDS expends $540,000 on rehabilitation-related research in traumatic brain injury.

Question. Can you describe some of these research efforts?

Answer. Several areas of advancement in basic research have emerged. These include: identification of growth factors present within the developing and injured nervous system that may prevent cell death and promote the growth of injured fibers; correlation of the morphological results of defined lesions with the physiology of the injured fiber tracts and the behavior of the animal; and identification of several molecules associated with outgrowth of nerve processes. For at least one of these latter molecules (GAP-43), the gene coding for the protein is known. Investigations are underway to delineate factors that can be used to turn the gene on and off.

Morphologic studies have demonstrated that lasers can be used to finely dissect the nervous system. The results of injury to single nerve fibers allow the study of the cellular and molecular biology of the nerve cell during axonal outgrowth or cell death. The goal is to determine the types of injury that are lethal to cells and devise ways to encourage regenerative processes.

In models of head injury, research is underway on the effects of several drugs, including inhibitors, scavengers of oxygen radicals, membrane stabilizers, calcium antagonists, potassium antagonists, and inhibitors of lipid peroxidation.

Question. What kind of research is currently ongoing related to the treatment of behavioral and cognitive abnormalities resulting from head injury?

Answer. Current research related to the treatment of behavioral and cognitive abnormalities resulting from head injury includes studies on the long-term behavioral and neurological sequelae of head injury. The results can be used prognostically to anticipate, and perhaps treat in advance, behavioral and cognitive abnormalities and can also be used as a guide to rehabilitation planning. In extensive studies of head injury in children, investigators are addressing fundamental hypotheses concerning the question of whether behavioral and cognitive abnormalities can be reversed in response to the ability of the immature nervous system to recover. They are also determining whether certain specific functions and abnormalities are more vulnerable to disruption by brain damage at specific ages. In terms of practical applications, the Institute is supporting the development of computer software for the remediation of certain academic and cognitive deficits in head trauma victims, specifically in young adults. This software is intended for use both in rehabilitation facilities and at home as part of the transition process back to community living.

## DEMENTIA

Question. More and more attention is being focused on dementia and other neurological symptoms sometimes associated with AIDS. How common is AIDS-related dementia and what are we doing to train our health professionals to diagnose this symptom?

Answer. AIDS-related dementia is a frequent neurological disorder which affects at least half of AIDS patients in the course of the illness. It is probably underdiagnosed since postmortem studies may reveal brain pathology in up to 95% of AIDS patients.

In our large urban hospitals young physicians are intensively trained in the care of patients with this illness. Training of the older practitioners must be accomplished through continuing medical education.

The NINCDS supports the training and clinical and basic research of biomedical scientists. Through their publications and lectures, NINCDS scientists and grantees are educating health professionals regarding AIDS-related dementia and other neurological complications.

Question. What impact does this development have on the kind of services needed by an AIDS patient?

Answer. With the development of dementia, AIDS patients progressively lose their independence. They eventually become totally dependent on others to help perform all activities of daily living. Assistance to terminally ill and demented patients is very demanding on care givers.

Question. What are we doing to provide the mental health services needed by those who have AIDS-related dementia?

Answer. The NINCDS supports fundamental and clinical biomedical research and research training that is being translated into better health for the nation. Our intense focus on AIDS of the nervous system is generating important new understandings of the infection and its impact on the nervous system and behavior. Mental health services will benefit from these investigations but are, of course, not directly supported by research funds.

## DECADE OF THE BRAIN

Question. Dr. Goldstein, would you please highlight the findings of the Report on the Decade of the Brain?

Answer. At the request of the House Appropriations Committee, the National Advisory Neurological and Communicative Disorders and Stroke (NANCDS) Council prepared a report to Congress which set forth neurosciences priorities and programs for the next ten years. The report, entitled "Decade of the Brain," concluded that basic and clinical scientists are rapidly advancing knowledge in areas relevant to neurological and communicative disorders. To ensure that research opportunities are exploited fully in the next decade, the NANCDS Council made two recommendations: First, the NINCDS appropriation for FY 1989 should be increased to $703,000,000; and, second, an entirely new mechanism, namely a Neuroscience Research Trust, should be created to deal with previously unaddressed issues related to research support for the neurosciences. The Council strongly urged Congress to establish a Neuroscience Research Trust that would provide the flexibility of rapid decision making regarding the funding of unusual opportunities to capitalize on exceptionally promising research of high priority. Of course, the Council did not consider other high competing priorities, such as AIDS and human genome research, when it made these recommendations.

Question. In your professional judgement, are there sufficient funds in the FY 89 budget to fund the recommendations and initiatives included in the report?

Answer. The Decade of the Brain report recommends a 1989 appropriation of $703,000,000. The 1989 request including AIDS is $570,978,000.

Question. How much more would be needed to implement these recommendations?

Answer. The difference between the recommendation of the Report and the Request is $132,000,000. Of course, funding the elevated level would require offsets against other public health activities, consistent with the Bipartisan Budget Agreement.

## EPILEPSY

Question. Dr. Goldstein, what new developments have there been in drug therapy for epilepsy since last year?

Answer. In fiscal 1988 the Institute initiated two pilot studies and one controlled clinical trial of potential new drugs.

In addition, the Institute sponsored a workshop where leading experts in epilepsy and representatives from the pharmaceutical companies and the FDA discussed problems and possible improvements in the design of controlled clinical trials.

The Institute also began evaluation, using a new animal model of drug tolerance, of a class of very promising antiepileptic drugs which have not proven useful in clinical practice because of the rapid development of tolerance in patients with epilepsy.

Question. How much will you spend in this area of research in FY 89?

Answer. In fiscal 1989 the Institute expects to spend $5,564,000 on drug therapy for epilepsy.

Question. How does that compare to FY 88?

Answer. The 1988 estimate is $5,161,000.

## BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. The NICHD's original request to NIH for FY 1989 was $498,239,000 for non-AIDS research activities, plus $20,310,000 for AIDS research.

Question. What was the Department's original request to the OMB?

Answer. The DHHS request to OMB for NICHD was $352,798,000 for non-AIDS research activities, and $15,460,000 for AIDS research.

## FTE's

Question. What was the original FTE request to the NIH Budget Office?

Answer. NICHD's original request to NIH was for 458 FTE's.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The FY 1989 President's Budget provides 423 FTE's for NICHD, compared to 424 FTE's in FY 1988.

## LEARNING DISABILITIES

Question. Dr. Alexander, as you know this Committee included language last year regarding the Report of the Interagency Committee on Learning Disabilities. The Committee directed you to take the lead in implementing the recommendations of the Report and I am told you have disseminated the Report, continued to host coordinating meetings of the Committee, and prepared an NICHD request for applications to develop four new program projects in learning disabilities research. How much would be required in FY 1989 to implement all of the recommendations?

Answer. Many agencies are represented on the interagency committee, and all of them would be involved in implementing the recommendations contained in the report. The report, however, contained no budget estimates, and the interagency committee has not developed any comprehensive budgets for implementing the recommendations. I would estimate that it would cost approximately $7 million in FY 1989 to implement the recommendations contained in the report, which are applicable to the NICHD.

Question. Specifically, how much is needed for new program projects for research training and for a research information clearinghouse?

Answer. The FY 1989 estimate for the four new program projects in learning disabilities is $3 million. To support more research training would require an additional $750,000, and the research information clearinghouse would cost $500,000. However, we have not identified appropriate offsets to remain within the Bipartisan Budget Agreement.

Question. Are these funds included in the President's request?

Answer. The President's request for FY 1989 does not contain funds for these activities. However, we will give these important issues priority consideration in future budgets.

## MENTAL RETARDATION CENTERS

Question. Dr. Alexander, will the President's FY 1989 budget request enable you to fund all existing mental retardation centers?

Answer. The FY 1989 President's Budget allows funding of 41 research centers, three fewer than the 44 centers funded in FY 1988. The three centers to be eliminated will be from the 10 centers scheduled for competing renewal in FY 1989. These 10 include three in demographic and behavioral sciences, four in reproductive sciences, and three in mental retardation.

Question. If no, how much more would you need to maintain all existing centers?

Answer. To maintain the Institute's 44 existing centers in FY 1989 at the same level as in FY 1988, i.e., with negotiated reductions of 17 percent, would require approximately $30,860,000 or

$1,747,000 more than the amount included for research centers in the FY 1989 President's Budget. To fund the 44 existing centers in FY 1989 at full cost would require $37,180,000, or $8,067,000 more than the amount included for research centers in the FY 1989 President's Budget.

## SUDDEN INFANT DEATH SYNDROME

Question. Dr. Alexander, how much is your Institute spending on research for sudden infant death syndrome?

Answer. In FY 1987, the Institute obligated $2,155,000 on research specifically directed to sudden infant death syndrome, (SIDS), and $23,421,000 on areas of high risk pregnancy and high risk infancy generally related to SIDS. The FY 1988 estimates are $2,300,000 and $24,800,000 respectively.

Question. How much are you requesting for FY 1989?

Answer. The Institute is requesting a total of $28,300,000 for research on SIDS under the FY 1989 President's Budget of which $2,400,000 is specific and $25,900,000 is generally related to SIDS.

Question. In your professional judgment, is that enough to fund the extent of the research our scientists are capable of conducting?

Answer. Much can be accomplished with the funds available in FY 1989. Additional funds could be used primarily to support research project grants to further the NICHD objectives in the SIDS research program. These are to expand the base of knowledge; to understand the causes and underlying mechanisms of the syndrome; to identify infants at risk for becoming victims; to explore preventive approaches; to clarify the relationship between high-risk pregnancy, high-risk infancy, and SIDS; and to elucidate the psychological impact of a sudden and unexpected infant death on parents, siblings, and the extended family. Further, additional funds would help reduce the level of negotiations in research project grants, the mechanism through which a significant portion of SIDS research is conducted, thus enabling investigators to undertake the full scope of approved projects. However, additional funds would require offsets against other public health activities, consistent with the Bipartisan Budget Agreement.

## BUDGET REQUEST

Question. What was the original request to the NIH budget office?

Answer. The original FY 1989 request to the NIH budget office was $238,013,000.

Question. What was the Department's original request to the OMB?

Answer. The Department's FY 1989 request to OMB was $134,847,000.

## FTE'S

Question. What was the original FTE request to the NIH budget office?

Answer. The original FY 1989 FTE request to the NIH budget office was 134 FTEs.

Question. How does that compare to the FTE allocation in the President's Budget?

Answer. The FTE allocation in the FY 1989 President's budget was 102 as compared to an FY 1988 FTE ceiling of 103.

## EPIDERMOLYSIS BULLOSA

Question. Dr. Shulman, have there been any recent advancements in research on epidermolysis bullosa?

Answer. This is a very active area of research in program activities. One of the recent advances in research on epidermolysis bullosa (EB) has been the identification of the structural regions and biochemical constituents of the skin's basement membrane zone, the area that is affected by EB. It has been found that a particular type of collagen, Type VII, is a major component of the structures that link the epidermis to the dermis. Characterization of this new collagen is yielding significant insight into its role in blistering diseases.

Also exciting is the discovery that the skin graft technique used to treat burn victims can be applied in the treatment of EB, providing both therapeutic benefits and a new model for investigation.

Question. How much are we currently spending on this disease?

Answer. It is estimated that we will spend $3.2 million in FY 1988 to support research on Epidermolysis Bullosa.

Question. How much have you requested for FY89?

Answer. We have projected $3.5 million for research on Epidermolysis Bullosa in FY 1989.

## LUPUS

Question. Dr. Shulman, I understand the Lupus Coordinating Committee met last year to report to the Congress on developments in lupus research. Would you please highlight some of the findings in the report?

Answer. The NIAMS, as the lead Institute for research on lupus, chaired and organized the Lupus Erythematosus Coordinating Committee and prepared the Committee's report to Congress. The report outlined advances and opportunities in lupus research as supported by several Institutes at the NIH. In just the past few years, positive research findings have emerged from such diverse areas as immunology, uncovering lupus in several important defects of the immune system; research on genetic determinants and environmental factors influencing the disease; studies of hormone metabolism; epidemiology; evaluations of the course and treatment of the disease and its complications; and studies aimed at developing improved therapies, including new drugs and techniques. The report describes several of these findings.

Question. In your professional judgment, are we spending enough in this area?

Answer. The NIAMS will fund an estimated $13.5 million for research on lupus in FY 1989. This represents a substantial level of research activity in this area.

## BUDGET REQUEST

Question. What was the original request to the NIH Budget Office?

Answer. The original NIGMS request to the NIH Budget Office for FY 1989 was $723.6 million.

Question. What was the Department's original request to the OMB?

Answer. The Department's original request to OMB for NIGMS was $547.6 million, but was predicated on base figures for FY 1988 included in the FY 1987 President's budget, rather than on the actual FY 1988 appropriated level.

## FTE'S

Question. What was the original FTE request to the NIH Budget Office?

Answer. NIGMS asked for 180 FTE's in its original FY 1989 budget submission.

Question. How does that compare to the FTE allocation in the President's budget?

Answer. The President's budget includes 158 FTE's for the NIGMS, compared to 160 FTE's in FY 1988 and 156 FTE's in FY 1987.

## HUMAN GENOME

Question. Dr. Kirschstein, what role does your Institute play in the research involved in mapping the human genome?

Answer. The National Institute of General Medical Sciences is playing a leading role at NIH in the support of research concerned with mapping the human genome. The initial approach to the ambitious task of mapping the entire human genome is not immediately directed toward learning about specific genetic diseases, or to identifying particular genes of interest--areas which are within the missions of the categorical Institutes. Rather, this first step involves developing the technologies necessary for the construction of detailed maps of the human genome and those of other organisms. The development of such detailed maps over the next 5-10 years will enable scientists to better understand human biology. The expansion of our knowledge of human biology is the specific mission of NIGMS. It is for this reason that Congress appropriated $17.3 million for the genome project to NIGMS in FY 1988, while the President's FY 1989 budget for NIGMS requests $28 million to expand this project. NIGMS plans to award an estimated 76 research project grants concerned with the special initiative to map and sequence complex genomes in FY 1988, and will play a major role in future activities.

Question. What recommendations do you have for this Committee on the level of funding and coordination needed to conduct this project?

Answer. Two important reports regarding the genome project have recently been issued, one by the National Academy of Sciences and one by the Office of Technology Assessment. Recommendations from these reports and from a recent meeting of an NIH Ad Hoc Program Advisory Committee on Complex Genomes suggest that funds be allocated for this project at increasing levels over a period of the next five years, finally reaching a steady state of $200 million per year. As I stated above, the President's budget request for FY 1989 includes $28 million for work related to mapping complex genomes. The NIH Ad Hoc Committee noted that funds are needed not only to support research and technological development, but also for research training and career development, for the development of new instrumentation, and for support of conferences to plan and coordinate the efforts required to characterize complex genomes.

In addition, in order to assure that proper coordination is achieved, the group recommended that NIH set up an Office of Human Genome Research in the Office of the NIH Director and charter a special program advisory committee. Both of these things are now being done.

The NIH Office of Human Genome Research will be responsible for integrating all NIH efforts into a cohesive plan, and will develop interagency coordination among NIH, other Federal agencies (DOE and NSF), and other research-funding organizations. It will also attempt to achieve collaboration with industry and academia, as well as international cooperation. This office will provide a central focus for the planning and implementation of the program for mapping and sequencing complex genomes. Along with the members of the program advisory committee, it will develop a series of specific proposals, with set goals, as called for in the National Academy of Sciences' Report. In this way, the entire effort directed toward characterization of the human genome and other genomes will be performed in the most efficient and effective manner possible.

## Budget Request

Question. What was the original request to the NIH Budget Office?

Answer. The NIEHS original request to NIH was $252,322,000, excluding the AIDS request of $4,234,000.

Question. What was the department's original request to the OMB?

Answer. The department's request to OMB for this Institute was $205,273,000, excluding the AIDS request of $4,234,000.

### FTEs

Question. What was the original FTE request to the NIH Budget Office?

Answer. NIEHS' original request to NIH was for 684 FTE's.

Question. How does that compare to the FTE allocation in the President's budget.

Answer. The President's budget includes 658 FTE's for this Institute.

### Lead

Question. What is the latest information regarding levels of lead in elementary school children's blood with hyperactivity and learning disabilities?

Answer. Since the release of the initial findings, now over a decade ago, which showed a correlation between elevated levels of lead in the baby teeth and increases in learning disabilities and hyperactivity in elementary children, the findings have been confirmed in additional studies. These studies were conducted both in the US and abroad and correlated blood lead levels with these conditions. More recent studies indicate that the neurotoxic and behavioral effects of lead can begin with exposures of the child to lead from the mother that passes into the fetus. It is our view that the blood level in children should not exceed 10 micrograms per deciliter, and that additional study is needed to learn how much lead can be absorbed each day by children without their exceeding a blood lead level of 10 micrograms per deciliter.

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## QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

### SPECIALIZED CENTERS OF RESEARCH IN DERMATOLOGY

Question. Dr. Shulman, what is the Institute's view of the need to expand the dermatology centers program to establish specialized centers of research (SCORs)?

Answer. In consultation with experts in the field of dermatology research, it was determined that the core center mechanism was the best type of center to support additional coordinated research in dermatology.

Question. Do you believe that the state of research capability in dermatology is such that SCORs would be both justified and beneficial?

Answer. We will make our first skin core center awards in late FY 1988. It seems wise first to evaluate the efficacy of that mechanism before determining the appropriateness of specialized centers of research in dermatology.

Question. What is the estimated cost of establishing a specialized center of research in dermatology in FY'89?

Answer. The estimated cost of funding a specialized center of research in FY 1989 is $900,000.

Question. How many would you recommend be established should necessary funding be available for that purpose?

Answer. Instituting still another research mechanism in addition to the skin diseases research core centers that are just being initiated, is not recommended. If such a center mechanism is determined to be appropriate, perhaps a minimum of three awards in a given research area might be made.

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## QUESTIONS SUBMITTED BY SENATOR PETE V. DOMENICI

### INTERSTITIAL CYSTITIS

Question. In its report of the last year, the Senate Sub-Committee on Labor, Health, and Human Services, Education, and Related Agencies stated that "The Committee believes that the Institute should continue to solicit research proposals on the etiology and treatment on Interstitial Cystitis and should give such proposals high priority, special consideration, and support. The Committee strongly encourages the allocation of supplementary funds to conduct basic research on Interstitial Cystitis at the established Kidney and Urologic Diseases Research Centers." Given this, why did NIDDK not issue an RFA in FY 1988? Why were no proposals on IC funded as result of the RFA issued in December 1986? If NIDDK has no plans to issue an RFA in 1988 how do they plan in 1989 to "continue to solicit research proposals on the etiology and treatment of IC?"

Answer. Although the 1988 Appropriation provided specific funds for new cystic fibrosis centers, no supplementary funds were provided for any of NIDDK's other centers programs, including the Kidney and Urologic Diseases Centers; and all existing centers are being funded at about the same levels as in 1987. It was therefore not possible to issue a new RFA for new centers or for expanded studies within existing centers.

The RFA for research grants issued in December 1986 was quite successful. We funded 7 proposals at a total cost of $1.2 million. We will continue to solicit proposals via three mechanisms. Firstly, we have recruited a new Urology Program Director who has both an M.D. and a Ph.D. He is thus very familiar with urologic research. Secondly, we are conducting a series of research workshops to broaden the research base in urology. Thirdly, we are completing the study of the diagnostic criteria required for the unequivocal diagnosis of interstitial cystitis.

Question. NIDDK representatives, Dr. Gary Striker and Dr. Charles Rodgers have written in their statement on IC which appeared in the Urology Supplement of April 1987 that NIDDK plans "to develop a Registry of interstitial cystitis patients in FY 1988." If, as stated, such Registry data is "fundamental to the development and design of controlled clinical studies," why has no allocation of funds been made for this purpose? Does NIDDK plan to develop such a Registry in the future.

Answer. The establishment of a registry or database requires firm criteria on which to base the diagnosis. Unfortunately there are no uniformly accepted criteria for its diagnosis among the urology investigators at the present time. Therefore, NIDDK convened a workshop in August 1987 for that purpose. Tentative criteria were established and two centers agreed to test them for one year. These data will be available in the fall of 1988 and will be evaluated in a second workshop. At that time, it will be possible to consider further clinical and basic scientific studies.

Question. NIDDK has stated that it has no budget plans in 1988 for an IC research center in spite of this Committee's encouragement to NIDDK to consider conducting basic IC research at one of the already established Kidney and Urologic Diseases Research Centers. Why is such a proposal not feasible at this time? And if not, what plans are there in 1989 for the establishment of such a center?

Answer. The proposal to conduct basic IC research at the existing Kidney and Urologic Diseases Research Centers is not feasible because of budgetary constraints. We will reconsider this in light of Congressional interest in future budgets.

## SUBCOMMITTEE RECESS

Senator CHILES. The subcommittee will stand in recess until Friday, perhaps.

[Whereupon, at 11:52 a.m., Thursday, April 28, the subcommittee was recessed, to reconvene at 9:30 a.m., Friday, April 29.]

# DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, AND EDUCATION AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 1989

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FRIDAY, APRIL 29, 1988

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
*Washington, DC.*

The subcommittee met at 12:08 p.m., in room SD–138, Dirksen Senate Office Building, Hon. Lawton Chiles (chairman) presiding.

Present: Senators Chiles, Specter, and Domenici.

Also present: Senator Mikulski.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### OFFICE OF THE SECRETARY

### STATEMENT OF HON. OTIS R. BOWEN, M.D., SECRETARY OF HEALTH AND HUMAN SERVICES

ACCOMPANIED BY:

WAYNE STANTON, ADMINISTRATOR, FAMILY SUPPORT ADMINISTRATION
SYDNEY OLSON, ASSISTANT SECRETARY FOR HUMAN DEVELOPMENT SERVICES
THOMAS R. BURKE, CHIEF OF STAFF, OFFICE OF THE SECRETARY
S. ANTHONY McCANN, ASSISTANT SECRETARY FOR MANAGEMENT AND BUDGET
DENNIS WILLIAMS, DEPUTY ASSISTANT SECRETARY FOR BUDGET

### OPENING REMARKS

Senator CHILES. Good morning.

Today the subcommittee is going to hear from Secretary Bowen testifying on the fiscal year 1989 budget request for the Department of Health and Human Services. Following his appearance, we will also hear testimony from Inspector General Kusserow.

During the next 2 weeks and for the last 2 weeks, the subcommittee has heard testimony from the several agency heads within the Department of Health and Human Services, and this session will provide a departmentwide overview, giving us an opportunity to discuss with the Secretary several issues that continue to be of concern.

Traditionally, the Secretary appears first. This approach lets the Secretary have the last word on major issues and problem areas before us.

In addition to the Secretary's prepared statement, we will include in the record a more detailed statement of the Family Support Administration and the Office of Human Development Services which we have not yet heard.

Mr. Secretary, let me summarize for you what I believe has been the subcommittee's reaction to the testimony received so far. We discussed with Dr. Wyngaarden the failure at NIH to reform the procurement system which, according to the inspector general and other sources, could achieve a 40-percent productivity improvement, saving some $26 million and 100 work-years annually.

Oversight over potential fraudulent science does not seem adequate, and these problems, if not corrected, could begin to undermine the consensus in this country that supports NIH.

The plan to cut another 3,300 staff from the Social Security Administration, at a time when the General Accounting Office reports a substantial rise in the error rate of processing old age and survivor's claims, was not well received.

Computer modernization, upon which the staff cuts are based, continues to lag behind schedule, while the Commissioner's own survey indicates that local office morale has plummeted.

With respect to immunization, the committee did not well receive the proposal to provide no funding for either State operation costs or the vaccine stockpile. Concern was also expressed about funding levels in efforts to control sexually transmitted diseases while we are experiencing alarming increases in the incidence of these diseases.

In other words, Mr. Secretary, we are funding all kinds of money for AIDS and everyone is rushing to do that, but at the same time we are seeing an explosion in different virulent strains of syphilis and gonorrhea and other sexually transmitted diseases. We do not see corresponding funds for those.

Despite the administration's contention that the war on drug abuse is a top priority, the research budget request for the National Institute on Drug Abuse actually drops below the 1988 levels. This is especially perplexing since the other two Institutes in the Alcohol, Drug Abuse, and Mental Health Administration would receive funding increases in the President's request.

In the area of health professions, we do not agree with your proposal to cut funding by $172 million from last year, and we do not agree with your proposal to consolidate all doctor, nurse, and allied health training programs into one grant program.

Proposed cutbacks in a number of antipoverty programs, including the proposal to eliminate the work incentive program and phase out the community service block grant and freeze Head Start to provide funding at $126 million below the authorized level were not well received.

Other programs that have had high priorities of Congress, such as child welfare, developmental disabilities, and older American activities, are also frozen below current services, and far below authorized levels.

Finally, the administration has requested cuts in refugee assistance and the low-income home energy assistance programs, and I do not think those will be popular. We will discuss those and other items today.

Senator Mikulski, do you have an opening statement you would like to make?

## STATEMENT OF SENATOR MIKULSKI

Senator MIKULSKI. Very briefly, Senator Chiles. I want to thank you for allowing me to join the subcommittee today.

I am going to welcome Dr. Bowen to the subcommittee. Over 20 percent of his HHS budget is spent in Maryland—the NIH is in Maryland, Social Security and HCFA in Woodlawn, as well close to 30,000 employees in our State.

In addition, HHS is vital to the Nation as the lead agency on such issues as the biocatastrophe of AIDS and the health care burdens we face with the greying of America.

Mr. Chairman, in my appearance here with you today at this subcommittee, I hope to be able to discuss, first, the drug testing guidelines that we have asked Dr. Bowen to develop so we could have a drug-free workplace; and then I would like to discuss the issues relating to Social Security and the situation at Woodlawn.

Thank you.

Senator CHILES. Thank you.

Secretary Bowen.

## OPENING STATEMENT HIGHLIGHTS

Secretary BOWEN. Thank you, Mr. Chairman and Senator Mikulski.

In the interest of time, I have shortened my presentation.

Senator CHILES. Your full statement will be included in the record.

Secretary BOWEN. Thank you.

I am pleased to present to you today the fiscal year 1989 budget of the Department of Health and Human Services. With me this morning are:

Mr. Wayne Stanton on my far left, who is Administrator of the Family Support Administration; and Ms. Sydney Olson, Assistant Secretary for Human Development Services, on my right. She will respond to key issues concerning the impact of the President's budget on the programs of her agency, as will Mr. Stanton on his agency.

Also with me is my Chief of Staff, Mr. Tom Burke, on my far right; and on my immediate right is Mr. Anthony McCann, Assistant Secretary for Management and Budget. They are present to discuss those accounts which fund the activities carried out in the Office of the Secretary. On my immediate left is Mr. Dennis Williams, Deputy Assistant Secretary for Budget.

The HHS budget calls for an outlay of $396.8 billion for a wide variety of health, income security and social services programs. It amounts to 36.3 percent of the Federal budget. For the Department's programs considered by this committee, our appropriation request totals $108.2 billion.

Federal entitlements are by far the biggest and fastest growing part of the HHS budget. Foremost among these are the Social Security, Old Age, Survivors and Disability Insurance Programs, with benefits of more than $228.4 billion.

Next in magnitude is Medicare, with net outlays of $84 billion. Then comes Medicaid, with outlays of $32.7 billion. Discretionary programs amount to almost $21.3 billion.

For the programs of the Public Health Service within this committee's purview, we are requesting $11.3 billion in budget authority. Three key elements comprise more than 75 percent of the PHS budget for 1989:

Some $7 billion for health research programs; $1.3 billion for health block grants for the States; and $1.3 billion for research and prevention efforts against acquired immune deficiency syndrome.

## ACQUIRED IMMUNE DEFICIENCY SYNDROME

In 1989, priority AIDS plans include:

Identifying newer AIDS viruses in the United States;

Continuing studies on the mechanisms of AIDS pathogenesis to understand how the human immunodeficiency virus progressively destroys the immune system;

Examining neuropsychiatric damages induced by HIV;

And establishing special projects to strengthen contact wih intravenous drug abusers.

## OTHER PUBLIC HEALTH SERVICE PROGRAMS

In 1989, $102 million is requested for the immunization program. The budget request provides for $93 million in grants to help States purchase childhood vaccines for their public immunization needs.

The immunization budget request also includes $8 million to continue the unique expertise in surveillance, research, and technical assistance of the Centers for Disease Control.

In 1989, nearly $400 million will be invested by the National Institute of Child Health and Human Development on maternal and child health research activities. The Institutes will continue research in areas such as prevention of low birth weight, fetal development, pregnancy and birth, roles of nutrients and hormones in growth and development, and causes and prevention of mental retardation.

In addition, $34 million is added to the maternal and child health block grant, and the $20 million infant mortality initiative begun in 1988 in conjunction with community and migrant health centers will be continued in 1989.

### DRUG ABUSE PROGRAM

A total of $596 million will be available for special drug abuse programs. In 1989, States will receive $166 million in special alcohol and drug abuse block grant aid for a wide array of treatment services.

These funds are in addition to the estimated $143 million used by States for drug abuse activities funded through the long-standing alcohol, drug abuse, and mental health block grant. In addition, communities will receive $93 million from our AIDS program to increase contact and treatment of intravenous drug abusers, important transmitters of the disease.

There will also be $41 million available to help communities develop strategies for preventing drug abuse; and the budget contains $153 million for research into drug abuse.

### HEALTH CARE FINANCING ADMINISTRATION

The total 1989 HCFA budget request for Medicare, Medicaid, and related programs includes net outlays of $116.8 billion.

For HCFA programs which require appropriations action, primarily Medicaid and a portion of the Medicare Program, we are requesting appropriations of $64.9 billion in 1989. This figure does not assume enactment of any proposed legislation.

### SOCIAL SECURITY ADMINISTRATION

The fiscal year 1989 budget for the Social Security Administration's income security programs for the aged, survivors, disabled and poor totals $247.9 billion in outlays, financed through both trust funds and general fund appropriations.

### FAMILY SUPPORT ADMINISTRATION

The fiscal year 1989 budget for the Family Support Administration totals $12.9 billion in net budget authority, including previously appropriated advances of $2.5 billion. Current law outlays total $13.4 billion. Pending welfare reform legislation would increase outlays by $168 million.

The family support payments to States include $10.9 billion in outlays for the aid to families with dependent children program and the child support enforcement program.

### HUMAN DEVELOPMENT SERVICES

We are requesting $6.2 billion for programs administered by the Office of Human Development Services for 1989. The budget increases funding for OHDS programs by $265 million over the 1988 level, principally for foster care and adoption assistance.

The proposed 1989 budget of $1.2 billion for Head Start maintains funding at the 1988 level and is an increase of $75 million over 1987. The 1989 request will allow Head Start to provide services to an estimated 454,000 children, while assuring quality of services.

The budget includes $1 billion for foster care and adoption assistance, of which $109 million is to pay State claims for foster care expenditures prior to 1987.

The 1989 budget requests $701 million for special programs operated by States and Indian tribes for the aged at the same level as 1988. The request will finance nutrition, transportation, in-home legal and community-based services for an estimated 14 million people, 6 million of them with low income. A major activity is the provision of a projected 237 million meals.

### PREPARED STATEMENT

These are some of the highlights of the 1989 budget for Health and Human Services. I believe it provides a sound basis for continued progress and service by my Department. I would be glad to answer whatever questions you may have.

[The statement follows:]

## STATEMENT OF OTIS R. BOWEN

I am pleased to have this opportunity to testify before you today on the 1989 budget of the Department of Health and Human Services.

This budget calls for an outlay of $396.8 billion for a wide variety of health, income security and social services programs and amounts to 36 percent of the Federal budget.

It is $21.6 billion higher than 1988, reflecting increases in benefits, more beneficiaries and the growing cost of health care. But our new budget also achieves outlay savings of $3.2 billion. For the Department's programs considered by this subcommittee, our appropriation request totals $108.2 billion.

Federal entitlements make up the overwhelming share of the HHS budget. Foremost among these are the social security programs, with benefits of more than $228.4 billion and accounting for almost 60 percent of dollar outlays. Next in magnitude is Medicare, with net outlays of $84 billion, or 21 percent of the budget. Then comes Medicaid, with outlays of $32.7 billion, or 8 percent of the budget.

Discretionary programs amount to almost $21.3 billion and are a mere 5 percent of the total.

This budget reflects the principles established between the Congress and the Administration at the Bipartisan Budget Summit in late 1987.

### PUBLIC HEALTH SERVICE

For the programs of the Public Health Service (PHS) within this Subcommittee's purview, we are requesting $11.3 billion in budget authority, representing an increase of more than 5 percent over the 1988 appropriated levels. This increase reflects the importance this Administration places on the programs that protect the health of all Americans.

Three key elements comprise more than 75 percent of the PHS budget for 1989: $7 billion for health research programs--other than those related to Acquired Immune Deficiency Syndrome (AIDS); $1.3 billion for health block grants to the States; and $1.3 billion for research and prevention efforts against AIDS, an increase of $349 million, or 37 percent, over the 1988 appropriations.

### ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS)

The 1989 budget includes $1.3 billion throughout PHS to support research on the causes and cures for AIDS as well as prevention and education efforts. Included in this total is $65 million for the Food and Drug Administration (FDA), which is not considered by this Subcommittee. This AIDS request represents a $349 million, or 37 percent increase in funding over the 1988 appropriation and will bring the total level of HHS resources expended on AIDS since 1982 to nearly $3.2 billion.

Expenditures on AIDS have been consolidated in a single appropriation account under the Assistant Secretary for Health in order to improve coordination and management accountability for the high level of resources being devoted to this top public health priority. Consolidating the AIDS funds will also increase research flexibility to respond to scientific breakthroughs as they occur. We believe consolidated funding will provide the same degree of flexibility and oversight possible in 1988 under the Department's transfer authority.

We are very proud of the extraordinary progress made in a relatively short period of time in understanding this new and devastating disease. On the scientific front, advances in epidemiological and biological research have enabled us to identify the virus that causes AIDS and to define its methods of transmission. A laboratory test to detect the presence of AIDS antibodies has been developed and is routinely used to insure a safe blood supply in this country. Initial vaccine clinical trials are currently in progress in the United States.

Additionally, the Department has established 19 new drug treatment and evaluation centers at regional medical centers around the country where there are over 25 active research protocols underway with an enrollment of over 2,900 patients.

In order to increase public awareness of AIDS and how it can be prevented, the Centers for Disease Control (CDC) has initiated a massive public information campaign. A general brochure which will provide facts about AIDS in a manner easily understood by the general public will be mailed later this year to every household in the country. Additionally, over 13 million copies of the October 1986 Surgeon General's Report on AIDS have been distributed. Public service announcements about AIDS transmission also have been developed and aired on local and national television and radio.

In 1989, additional expenditures will occur in all aspects of the PHS-supported AIDS research and prevention activities. Our priority plans for the immediate future include:

- Conducting a national set of surveys to measure the prevalence and incidence of HIV infection, and developing optimal models to project future trends;
- Identifying newer AIDS-related viruses in the U.S. such as HIV-2 and developing appropriate screening tests;
- Continuing studies in the mechanisms of HIV pathogenesis to understand how this virus progressively destroys the immune system;
- Examining neuro-psychiatric damages induced by HIV, especially during the early phases of infection;
- Establishing special projects to strengthen contact with intravenous drug abusers in order to induce positive behavior changes;

- Developing a nationwide program to support the worldwide search for potential new agents for the treatment of AIDS;
- Expanding the Phase I clinical trials, begun recently, of the first potential candidate vaccines against HIV;
- Helping improve patient care practices and other supportive services for AIDS patients, especially with a view towards out-of-hospital care; and
- Expanding information/education efforts.

The Department is reviewing the recommendations of the Chairman of the Presidential Commission on the Human Immunodeficiency Virus (HIV) to the full Commission. In general, we agree with the thrust of a majority of the recommendations. Our differences are primarily over the magnitude of some of the recommendations. The appropriate agencies are now conducting a thorough analysis of the report.

## HEALTH RESEARCH

In addition to AIDS activities which cross agency lines throughout PHS, the 1989 request includes $6.5 billion in budget authority for the National Institutes of Health (NIH), and $484 million for the Alcohol, Drug Abuse and Mental Health Administration (ADAMHA). These funds will continue support for basic biomedical and behavioral research, the development of scientists, and the demonstration of clinical applications that will be translated into future long-term improvements in medical care and the health of the American people. Because of this commitment to basic health research, the United States continues to be the world leader in biomedical science, and attests to the Administration's commitment to the excellence achieved by these two research institutions.

The principal element of the request is $3.9 billion for the support of over 20,600 research project grants. These projects are funded by NIH but performed by university-based scientists. The 1989 level of 20,600 research projects represents the highest number of research project grants ever supported by the NIH. This is a dollar increase of over 8 percent and includes 837 more projects than the comparable 1988 level, while at the same time providing the average noncompeting grant with almost a 5 percent increase over 1988 and the average new/competing grant with about a 3 percent increase over 1988. As indicated earlier, it is important to recognize that this portion of the budget request does not include the funds requested for AIDS.

In addition to grants supported through extramural funding, the NIH intramural program serves as a unique national resource; standing on the frontier of new, emerging areas in biomedical science, it is, by its very nature, able to respond more quickly to new ideas and changing directions as scientific needs change. Additionally, NIH's intramural laboratories serve as the training ground for a large portion of this nation's university-based scientists. In recognition of the role intramural research plays in the overall national research effort, our request includes $671 million for this program, an increase of almost 4 percent.

Additionally, a study is being commissioned through the Institute of Medicine of the National Academy of Sciences to evaluate strategies to assure continued scientific excellence of the NIH intramural laboratories. In light of Federal salary, procurement, construction, travel and personnel ceiling limits, the study will examine the intramural program vis-a-vis its overall placement in a large bureaucracy and a broad range of options for the organizational structure and authorities of the NIH intramural program. A final report is expected later this year.

Similarly, the ADAMHA budget requests $484 million to support approximately 1,650 extramural research project grants in 1989. The average cost per grant will also increase 5 percent.

When viewed in the context of the Bipartisan Budget Agreement's 2 percent rate of growth limitation for domestic discretionary spending, this request illustrates the Administration's resolve to address the issues of alcohol and other drug abuse, mental illness and other elements directly related to homelessness. A major strategy to achieve success in these areas is a commitment to invest in the future through devoting significant resources to research. This comes at a time for justifiable optimism on the part of scientists seeking solutions to mental health disorders and alcohol and other drug abuse.

## HEALTH BLOCK GRANTS

A total of $1.2 billion is included in the 1989 budget for health block grants. These funds are an important investment in the health of America. Our health block grant programs serve as a principal means for assisting the States in meeting their priorities in areas such as maternal and child health, preventive health, and alcohol, drug abuse and mental health services. They are the primary funding mechanism for distributing Federal financial assistance and provide the States flexibility to plan and implement activities to meet their own service requirements. The States have exercised their direction over these funds to reduce infant mortality, promote healthy lifestyles, and help individuals solve their substance abuse problems.

Included in the $1.2 billion total is $561 million for Maternal and Child Health, a 6 percent increase; $86 million for Prevention, the same level as in 1988; and $509 million for the Alcohol, Drug Abuse and Mental Health block grant, a 4 percent increase over 1988.

In addition, we are requesting funds in 1989 for two other major grant programs that provide direct funding to States to meet emerging health needs:

- $140 million to carry out our legislative proposal to consolidate family planning funding at the State level; and
- $166 million for the special Alcohol and Drug Abuse Treatment and Rehabilitation grants, an increase of $10 million over 1988. This program was established by the Anti-Drug Act of 1986.

## OTHER AREAS OF SPECIAL CONCERN

### Immunization

In 1989, $102 million is requested for the immunization program, a net increase of $3 million over the 1988 level. Through the leadership of CDC and the provision of financial assistance to States, this investment in health has reached record levels of coverage; over 95 percent of our children entering school are now protected. Many childhood diseases, such as measles, mumps, rubella, tetanus, diphtheria, and polio have been brought almost entirely under control.

The budget request provides for $93 million in grants to maintain these achievements by helping States purchase childhood vaccines to address their public sector immunization needs; this is a $7 million increase over 1987. Funds in the request are sufficient to purchase in 1989 the same number of vaccine doses as were provided in 1988. The immunization budget request also includes $8 million to continue CDC's unique expertise in surveillance, research, and technical assistance.

### Infant Mortality

The Department is continuing to focus efforts on reducing rates of infant mortality in this country. While infant mortality rates have declined markedly over the past 20 years, the latest rate from 1986 of 10.4 per 1,000 live births indicates a need for continued and increased attention.

A major source of support for addressing this problem is the National Institute of Child Health and Human Development, which will continue research in areas such as prevention of low birthweight, a critical factor in reducing infant mortality; fetal development; pregnancy and birth; roles of nutrients and hormones in growth and development; and causes and prevention of mental retardation. In 1989, nearly $400 million will be invested by the Institute on the maternal and child health and human development research activities.

To encourage greater State activity in the areas of prenatal care and infant mortality, the 1989 budget includes $561 million for the Maternal and Child Health block grant, an increase of $34 million over the 1988 level.

In addition, the $20 million infant mortality initiative begun in 1988 in conjunction with Community and Migrant Health Centers will be continued in 1989. Under these special programs, prenatal care services will be provided to at least 25,000 low-income women located in areas with excessive infant mortality levels.

Pressing Social Issues

Public attention has increasingly been drawn to the problem of drug abuse and homelessness and their impact on society. The 1989 budget targets resources to complement community efforts in providing services to those persons in need. A total of $596 million, an increase of $73 million, will be available for special drug abuse programs. Also, HHS will fund $93 million in 1989 for homeless demonstration projects in health care and mental health services to augment existing social services programs through PHS, FSA, OHDS and HCFA.

The President's initiative for a drug-free society will reduce the demand for drugs by increasing treatment and prevention services through the partnership of Federal, State, and local government and private organizations. As mentioned earlier, in 1989, States will receive $166 million in special alcohol and drug abuse block grant aid for a wide array of treatment services. States are targeting their resources on the most vulnerable segments of the population: children and adolescents. These funds are in addition to the estimated $143 million used by States for drug abuse activities funded through the alcohol, drug abuse and mental health block grant. In addition, communities will receive $93 million to increase contact with and treatment of IV drug abusers, an important population in the transmission of AIDS.

Prevention measures are a critical component in the fight against drugs and in 1989 there is $41 million available to help communities develop strategies for preventing drug abuse. Research is the foundation for all of our knowledge as to how to best treat and prevent drug abuse. The 1989 budget contains $153 million to further scientific explorations and understandings in the field of drug abuse research.

Health Professions

The 1989 budget requests $40 million for health professions education. I am proposing legislation to consolidate the numerous categorical grant activities of the past. Funds will be awarded to States, groups of States, consortia of non-Federal institutions, or other entities to promote the training of health professionals in priority areas such as family medicine, geriatric health care, and professional nursing. Training opportunities for minorities and disadvantaged students will be emphasized. The new program will allow increased attention to the expanding elderly population, will develop the capacity to care for people as outpatients, rather than on the more costly inpatient basis, and will train health care professionals, such as nurse practitioners, committed to providing care to rural and other underserved populations.

## HEALTH CARE FINANCING ADMINISTRATION

The total 1989 Health Care Financing Administration (HCFA) budget request for Medicare, Medicaid and related programs includes net outlays of $116.8 billion, an increase of $7.2 billion over the current estimate for 1988.

Approximately 54 million beneficiaries will be served through the Medicare and Medicaid programs in 1989. The HCFA budget is based on a policy of responsible deficit reduction through increased efficiency and savings proposals aimed at reducing unnecessary and unwarranted spending, while maintaining high quality health care for program beneficiaries.

This budget reflects the Administration's strong commitment to meet the health needs of the elderly, disabled and poor and to strengthen the focus on quality of care. The budget request includes a number of legislative proposals which are expected to save the Medicare program approximately $1.2 billion in 1989. Another proposal would increase revenues by $1.6 billion in 1989 by providing Medicare coverage to all State and local employees.

For HCFA programs which require appropriations action -- primarily Medicaid and a portion of the Medicare program -- we are requesting appropriations of $64.9 billion in 1989. This figure does not assume enactment of any proposed legislation.

### MEDICAID

The Administration is requesting a two-year appropriation for Medicaid. The 1989 appropriation requested is $32.7 billion. This includes $8 billion that has already been appropriated in advance for the first quarter of 1989. In addition, $35.8 billion is requested for 1990 and $9.8 billion for the first quarter of 1991. The 1989 budget is based on the November 1987 States' Medicaid estimates and includes the impact of regulatory and administrative initiatives which would have a net budget effect of $413 million in 1989 and $540 million in 1990.

In addition to the regulatory and administrative initiatives, one Medicare proposal is expected to have an impact on Medicaid. The Medicare budget proposes to make the 25 percent beneficiary share of the Medicare Part B program permanent. This will affect States who pay for this portion of Medicare for their Medicaid recipients beginning in 1990. It is anticipated that this measure will cost $20 million in 1990. There are no other legislative proposals within the Medicaid program.

### PAYMENTS TO HEALTH CARE TRUST FUNDS

A total of $32.1 billion is requested for the Payments to the Health Care Trust Funds appropriation in 1989, an increase of $6.2 billion above 1988, and $35.1 billion is requested for 1990. This account reflects certain general revenue payments to Medicare, the largest being the Federal share of costs for individuals enrolled in the Medicare Supplementary Medical Insurance program (Medicare Part B). The appropriation request represents approximately 75 percent of total Part B program costs. Enactment of 1989 Medicare legislative proposals included in the President's Budget would reduce the Payments to Health Care Trust Funds request by a total of $205 million.

## PROGRAM MANAGEMENT

The 1989 budget request includes $95 million in appropriations and $1,663 million in trust fund transfer authority to administer the Medicare and Medicaid programs. The program management appropriation includes the following:

### Medicare Contractors

A total of $1,391 million is requested for Medicare Contractors, an increase of $168 million above 1988. This year, however, we are not requesting a contingency fund specifically earmarked for unanticipated workloads, as in the past. Approximately 66 percent of the budget request for Medicare Contractors, or $923 million, is allocated to claims processing services. The amount requested is sufficient to process an estimated 477 million claims, an increase of 38 million over 1988. This request also includes $65 million in productivity investments, slightly more than double the 1988 level. The combined effect of paying a market price for processing claims, productivity gains and innovative contracting strategies stem, in part, from the growth in expenditures in this activity. The remainder of the request will be used largely to assess the quality and appropriateness of health services provided to beneficiaries.

### State Survey and Certification

The $66 million request provides for 1,200 additional surveys of Medicare providers and reflects the Administration's strong commitment to ensuring that program beneficiaries receive quality care.

The 1989 request supports survey coverage of approximately two-thirds of the facilities participating in Medicare. This level will provide annual inspections of all skilled nursing facilities and hospices. In 1989, significant refinement of this survey and certification process will be made through development of better survey instruments, expansion of data bases and improved surveyor training.

### Research

A program level of $32 million is requested for the research, demonstration and evaluation program in 1989. Priorities will include: further refinement of the hospital prospective payment system; testing the feasibility of capitated systems, including the exploration of innovative arrangements patterned after private sector developments such as preferred provider organizations and negotiated agreements;

and development and testing of alternative payment systems for skilled nursing facilities and physicians. Additional research efforts will focus on quality of care, subacute and long-term care, program efficiencies analysis and beneficiary awareness.

## Federal Administrative Costs

A total of $271 million is requested for Federal Administrative costs, $18 million more than in 1988. Of this total, $15 million will be used for development and purchase of a computer information system which will provide improved and more accessible data bases. The rapidly evolving Medicare program requires faster, more sophisticated analysis of program data. This new computer system will assist HCFA in responding in a timely manner to legislative and policy-related inquiries.

The request will support 4,096 FTE in 1989, an increase of 267 over the end of 1987. This increase includes 63 FTE to handle increased workload, 50 FTE for implementation of Catastrophic Health Insurance and 154 FTE for Medicare Part B appeals.

## SOCIAL SECURITY ADMINISTRATION

The 1989 budget for the Social Security Administration's (SSA) income security programs for the aged, disabled and poor totals $247.9 billion in outlays financed through both trust funds and general fund appropriations. These programs, which constitute over 60 percent of HHS budget outlays, will provide benefits to about 42 million people in 1989.

For programs subject to appropriations, we are requesting $13.4 billion for 1989. In order to streamline the process for considering appropriated entitlements, we are also requesting $13.1 billion for 1990 and $2.9 billion of advances for the first quarter of 1991.

In 1989, SSA will continue its emphasis on improving services and implementing its Systems Modernization Plan. Newer, faster data systems have been installed, cutting time required to serve beneficiaries. Productivity and service improvements are expected to continue at an even greater pace over the next few years. Installation of a new "800" telephone number will insure greater public access to information concerning their records and benefits. The appropriation request by program is as follows:

## SUPPLEMENTAL SECURITY INCOME

The 1989 appropriations request for the Supplemental Security Income (SSI) program is $12.5 billion, including an appropriated advance of $2.8 billion. In addition, $12.3 billion is requested for 1990 and $3.4 billion for the first quarter of 1991. Federal benefit payments under this program will provide assistance to an average of 4.2 million recipients each month in 1989.

This request supports the Administration's commitment to cost-of-living increases of 4.2 percent payable in January 1989 and in January 1990. This brings the maximum allowable Federal benefit amount to $354 per month for an individual and $532 per month for a couple in 1988. In 1989, these amounts increase to $369 per month for an individual and $554 for a couple.

Despite this cost-of-living adjustment, benefit payments in the 1989 budget reflect an estimated decrease of $29 million over 1988. Twelve monthly benefit payments for 1989 are included compared to 13 monthly payments in 1988, thus accounting for a substantial portion of the decrease in benefit payments. This decrease in the number of checks is partially offset by the COLA payments, as well as by a projected increase of 121,000 SSI recipients.

## SPECIAL BENEFITS TO DISABLED COAL MINERS

The 1989 appropriations request for Special Benefits to Disabled Coal Miners is $879 million including an already appropriated advance of $250 million. The request for 1990 is $848 million and for the first quarter of 1991 is $2 million. Federal benefit payments under this program will provide assistance to an average of 236,000 recipients each month.

The 1989 request is $39 million below the 1988 appropriation, primarily due to the continuing decline in the number of beneficiaries receiving payments administered by SSA. It is expected that the number of beneficiaries will decline by an additional 18,000 in 1989. This decline is due not only to the death of disabled coal miners, but also to the declining population of widows entitled to survivors benefits under the program.

## PAYMENTS TO THE SOCIAL SECURITY TRUST FUNDS

The 1989 appropriations request for payments to Social Security Trust Funds is $94 million and for 1990 is $85 million. Since 1988, we no longer request funds in this account to reimburse the trust funds for military service wage credits for current uniformed personnel. These funds are requested by the Department of Defense, PHS, National Oceanic and Atmospheric Administration, and the Coast Guard so that the costs of uniformed personnel are more accurately reflected in the budget.

## LIMITATION ON ADMINISTRATIVE EXPENSES

The Limitation on Administrative Expenses (LAE) provides resources for SSA to administer the Old Age, Survivors and Disability Insurance programs, certain health insurance functions and the SSI program.

For 1989, we are requesting new obligational authority of $3,776 million, $28 million less than in 1988. The request includes a contingency reserve of $48 million.

SSA is also continuing to benefit from administrative improvements and the hundreds of millions of dollars invested in systems modernization. The FTE target for 1989 is 65,045, down 4,300 from the 1988 total. We are confident that this combination of financial and staffing resources will be adequate to maintain the high quality of service that the public has come to expect from SSA.

## FAMILY SUPPORT ADMINISTRATION

The 1989 current law budget for the Family Support Administration (FSA) totals $12.9 billion in net budget authority, including previously appropriated advances of $2.5 billion, with total outlays of $13.4 billion. Pending welfare reform legislation would increase outlays by $168 million. Priorities in 1989 include: (1) support of welfare reform through the Aid to Families with Dependent Children (AFDC) Employment and Training Reorganization Act of 1987; (2) improving the coordination between AFDC and Child Support agencies to increase collections on behalf of AFDC recipients; (3) increasing child support collections; and (4) limiting selected discretionary spending to further aid the deficit reduction targets.

### FAMILY SUPPORT PAYMENTS TO STATES

The Family Support Payments to States includes $10.8 billion in outlays for the AFDC and Child Support Enforcement programs. No new legislation is proposed as part of the 1989 budget request for Family Support Payments to States. However, $168 million in increased outlays is included in the budget for the costs of implementing the AFDC Employment and Training Reorganization Act of 1987, S. 1655 and HR 3200, the welfare reform legislation which the Administration supports.

This pending legislation would reform AFDC work and training programs, strengthen the Federal-State child support enforcement system and provide broad flexibility to current programs which support low-income families and individuals.

### Aid to Families With Dependent Children

Total appropriations of $9.9 billion have been requested for assistance payments in 1989. Under current law, these funds will provide assistance to an estimated 3.8 million families each month. Funds for the first quarter of 1989, $2.5 billion, have already been provided under the advance appropriation authority.

### Child Support Enforcement

Total 1989 appropriations requested for the Child Support Enforcement program are $900 million. This represents an increase of $128 million over 1988. Added to incentive payments, this will provide States with $1,170 million in Federal funds -- about 90 percent of program cost. Funds also are included in 1989 in the FSA program administration budget to build on previous FSA investments to address the problem of unpaid child support obligations in interstate cases. When complete, a self-supporting telecommunications network will link all States, facilitating rapid information exchange and increasing the effectiveness of interstate enforcement of this program.

## LOW INCOME HOME ENERGY ASSISTANCE PROGRAM

The 1989 budget requests a $1.2 billion appropriation for the Low Income Home Energy Assistance Program (LIHEAP), a reduction of $345 million compared to 1988. This strategy is appropriate because of additional energy-related resources States have available to apply against the home energy assistance needs of their low-income citizens. States still have available $1.3 billion from prior-year overcharge settlements and additional settlement funds over and above those already received by the States are expected to be distributed to the States during 1988 and 1989. In view of the fact that energy prices have stabilized, States and private contributions are responding to low-income needs, and weatherization has progressed, such that the need for large Federal assistance has diminished.

## REFUGEE AND ENTRANT ASSISTANCE PROGRAM

The budget request for 1989 for the Refugee and Entrant Assistance Program totals $279 million in budget authority. This level of funding is sufficient to subsidize 100 percent of State costs in the provision of services for 24 months to refugees and entrants with categorical eligibility for Federal welfare programs, and for 12 months to individuals without such eligibility. In addition, this will support 12 months reimbursement of States' General Assistance costs for refugees without AFDC eligibility status.

## COMMUNITY SERVICES PROGRAMS

In 1989, $310 million is requested as part of a four-year phaseout of Community Services programs. States may use other sources of funding, including the Social Services Block Grant, to support those community services activities which are of the highest priority and most effective. The phaseout approach will give local grantees adequate time to identify funding from other Federal, State, local and private sources. No funds are requested for Homeless grants or for Community Food and Nutrition activities since such assistance is available through other Federal programs.

## FEDERAL PROGRAM ADMINISTRATION

A total of $80 million is requested to administer all FSA programs, including $3 million for research and evaluation activities and $3 million to complete the development of a self-supporting child support enforcement telecommunications network.

## OFFICE OF HUMAN DEVELOPMENT SERVICES

We are requesting $6.2 billion for programs administered by the Office of Human Development Services (OHDS) for 1989. The 1989 budget continues the policies of this Administration to support State social services and related programs which promote self sufficiency among program recipients, while focusing Federal resources on the most effective and efficient programs, and emphasizing the role of the family in preventing dependency. The budget increases funding for OHDS programs by $265 million over the 1988 level principally for foster care and adoption assistance.

### BLOCK GRANTS

The 1989 budget request provides for the Social Services Block Grant at the full authorization level of $2.7 billion.

Child day care, child and adult protective services, home management and maintenance services, employment and legal services, and transportation are some examples of social services offered by the States.

### HEAD START

The proposed 1989 budget of $1.2 billion maintains funding at the 1988 level, an increase of $75 million over 1987.

The 1989 request will allow Head Start to provide services to an estimated 454,000 children while assuring quality of services. This is an increase in the number of children served of 7,500 over 1987. In addition, in order to improve services, Head Start will continue to identify and implement innovative and cost-effective approaches in providing Head Start services.

### FOSTER CARE AND ADOPTION ASSISTANCE

For 1989, the budget requests over $1 billion for Foster Care and Adoption Assistance. The 1989 request includes $109 million to pay State claims for foster care expenditures prior to 1987.

These resources will fund programs to keep families together, support children who cannot continue to live with their families, provide adoptive homes when reunification of children and families is not possible, and support research and demonstration designed to strengthen families and reduce barriers to the adoption of children with special needs.

The budget requests $832 million for the Foster Care program to provide maintenance payments for children who must live outside their homes. This is an increase of $174 million over the 1988, and a slight increase in the average monthly number of children in foster care to 115,000 children. The 1989 request includes $109 million for prior-year claims, including administrative costs.

The request of $134 million for Adoption Assistance represents and increase of $26 million over the 1988 appropriated level. This request reflects increased State expenditures and continued growth in the number of children assisted to nearly 44,000 children.

The budget request does not assume reauthorization of the Independent Living program. The two-year authority for this new activity expires in 1988. States can support similar services through existing social services programs.

## AGING PROGRAMS

The 1989 budget requests $701 million for special programs operated by States and Indian Tribes for our aged population, the same level as in 1988. The request will finance nutrition, transportation, in-home, legal and community-based services. The amounts budgeted will assist an estimated 14 million people in Aging programs, of whom 6 million will be low-income participants. Over 670 Area Agencies and 57 State Agencies on Aging will also be supported. A major activity is the provision of meals, and in 1989 nearly 236 million meals are projected to be served.

## OFFICE OF THE SECRETARY

The 1989 budget also includes $136 million requested for activities in the Office of the Secretary's (OS) account under jurisdiction of this Subcommittee. This amount does not include $51 million requested for transfer from the various Social Security and Medicare and Medicaid trust funds. Within OS are the following activities: General Departmental Management (GDM), the Office of Inspector General (OIG), the Office for Civil Rights (OCR), and Policy Research (PR).

For 1989, the budget proposes for GDM a staffing increase of 14 full-time equivalent (FTE) staff years over 1988, to cover additional workload in the Office of the General Counsel.

In 1989, the OIG will continue to direct its efforts and resources on the Social Security and Medicare programs. Dollar savings, through fines, restitutions, recoveries and penalties, as well as successful prosecutions, are expected to continue at the levels achieved during the past several years. The 1989 budget proposes a staffing increase of 66 FTE over 1988. The increase in 1989 will allow the OIG to respond to increased legislative sanctioning, enforcement and related authorities, assure proper implementation of Immigration Reform legislation provisions, and continue oversight, monitoring and auditing of HHS programs and activities.

Our obligations to assure civil rights compliance among the Department's federally-assisted programs and services will be carried out through this budget. The budget request permits OCR to continue its broad-scale compliance program, which includes voluntary compliance, reviews of recipient compliance, and investigation of complaints of discrimination.

The funds requested for Policy Research in 1989 enable the Department, under its only flexible research authority, to work on issues of national policy significance in the health care, income assistance and human services fields.

The Working Capital Fund was restored in 1988 and the costs of centralized services are displayed in the Operating Divisions' individual budget requests.

These are some of the highlights of the 1989 budget for health and human services. I believe it provides a sound basis for continued progress and service by my Department. I would be happy to answer any questions at this time.

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## BIOGRAPHY OF OTIS R. BOWEN

Otis R. Bowen, M.D., was sworn in as secretary of health and human services Dec. 13, 1985, by U.S. District Court Judge Sarah Evans Barker. He was nominated by President Reagan Nov. 7, 1985, and confirmed by the Senate Dec. 12, 1985.

As head of the Department of Health and Human Services, Dr. Bowen oversees the federal agency responsible for the major health, welfare, food and drug safety, medical research and income security programs serving the American people.

A former two-term governor and member of the state House of Representatives in Indiana, Dr. Bowen came to HHS from the Indiana University School of Medicine in Indianapolis where he was serving as Lester D. Bibler professor of family medicine and director of undergraduate family practice education.

Dr. Bowen was born in Richland Center, Ind., Feb. 26, 1918. He received a bachelor's degree in chemistry from Indiana University in Bloomington in 1939 and his M.D. degree from the Indiana University School of Medicine in 1942. He interned at Memorial Hospital in South Bend, Ind., 1942-1943, and served in the Pacific Theatre during World War II as a member of the U.S. Army Medical Corps, 1943-1946.

Dr. Bowen was coroner in Marshall County, Ind., from 1952 to 1956. He served as a Republican member of the House of Representatives in Indiana in 1957, 1958 and 1961-1972, serving as Minority Leader, 1965-1966, and as Speaker for three terms, 1967-1972. He was governor of Indiana from 1973-1981.

He has served on a number of federal advisory bodies, including: chairman, Advisory Council on Social Security, 1982-1984; member, Presidential Advisory Committee on Federalism, 1981-1983; member of the Advisory Commission on Intergovernmental Relations, 1977-1979; President's Committee on Science and Technology, 1976-1977; and member of the Commission on Federal Paperwork, 1975-1977.

Other bodies he has served on include the Two Year Study on Nursing and Nursing Education, Institute of Medicine, National Academy of Sciences, 1981-1983; and the Education Commission of the States, 1973-1983 (chairman, 1978-1979).

Medical organizations in which Bowen holds memberships are the Marshall County Medical Society, Marion County Medical Society, Indiana State Medical Association, 13th District Medical Society, Indiana Academy of Family Physicians, the American Academy of Family Physicians and the American Medical Association.

Bowen has received honorary doctorates from 26 institutions of higher education including Indiana University, Indiana State University, Ball State University, University of Notre Dame and Purdue University. He received five in 1987 from Indianapolis University, Wabash College, University of Maryland, New York Medical College and the College of Medicine, Baylor University.

Honors and awards received by Bowen include the merit award of the Indiana Public Health Association, its highest honor bestowed on an individual, for outstanding achievement in health; and the AMA's first Benjamin Rush Award for outstanding contribution by a physician in citizenship and public service.

He is a member of the Kiwanis Club, Phi Beta Pi, Alpha Omega Alpha, Delta Chi and Family Practice Club, IAFP.

Dr. Bowen has written extensively on health, welfare and educational matters.

He is married and has four children. He is residing in Alexandria, Va.

### DRUG TESTING GUIDELINES

Senator CHILES. Thank you.

Senator Mikulski, would you like to question him?

Senator MIKULSKI. Thank you very much, Mr. Chairman. First I have just one set of questions, if I may, on the Federal employee drug testing guidelines developed by HHS.

As you know, we are striving for a drug-free workplace, but within the Federal policies developed by President Reagan and this Congress, there must be employee confidence in the laboratory aspects. And Dr. Bowen, I know that you, at our request, have developed and issued drug testing guidelines about 2 weeks ago.

They are generally very good, and particularly on the lab certification. I would like to ask you, however, a couple of questions about them.

Two areas that I would like to pursue in that area before moving to Social Security. Your drug testing guidelines require a site collection person to administer and monitor the drug test. And as a physician, you know that the two most important aspects of drug testing are the way a specimen is collected and then of course the way it goes through the actual laboratory test.

Do you have—and I did not note this in your promulgated guidelines—specific training standards and background checks for the people who will be collecting the specimens?

Secretary BOWEN. There will be extensive education given to these individuals through the ADAMHA. I do not have an outline with me, but it will be an educational effort.

Senator MIKULSKI. No; I understand that. What I would like to have from HHS is what the requirements for these people will be: what will be the educational requirements, how extensive will the background checks be, and what kind of training will the collection technicians have so that we can ensure that as these specimens are collected among the Federal employees there will be uniformity and consistency with the collection techniques and with the type of personnel who will be used?

[The information follows:]

### DRUG TESTING REQUIREMENTS

The minimum qualifications of the site collection person are: same gender as employee, ability to read instructions, verify picture ID of employee, prepare the site collection room, order and handle supplies, handle security of specimens, prepare for shipment, and respond to questions on procedures asked by employee.

BEST AVAILABLE COPY

Over 22 agencies have indicated they will purchase collection services from a contract to be awarded by DHHS/NIDA. The contractor will be responsible for hiring staff and implementing a drug testing program for its own staff as a condition of award.

Contractors which provide collection services will be responsible for training their employees. The National Institute on Drug Abuse, Office of Workplace Initiatives is developing a handbook on collection services to use as guidance for the agencies' drug program coordinators. Based on the training need in the agencies, NIDA will collaborate with OPM on making this training.

### REQUIREMENTS

Senator MIKULSKI. The second question, Doctor, goes to the scientific methodology and, of course, costs of these tests. There are those who are concerned about false positives and would like to see the concept of sample splitting used, meaning when a specimen is taken or a sample is taken one-half would go to the laboratory for evaluation, another one-half would be placed in a safeguard position.

If there is a positive, there would be the opportunity for a second opinion on the same sample. Has there been consideration given to that?

Secretary BOWEN. I think that is a necessity, and yes, I think that is something that is taken for granted by ADAMHA. I am sure it is in writing.

Senator MIKULSKI. Doctor, I would like to ask you then to go back and take a look at the guidelines. I did not see that they required sample splitting.

Now, I must tell you, when you read guidelines you do not always get every point. But I did not see that component there. And if we could go back and give a second opinion on the guidelines, it would be most helpful to really ensure that the issue of sample splitting is provided for.

[The information follows:]

### DRUG SAMPLE SPLITTING

The collection site person may only have the employee provide a second sample under direct observation if, as stated in the mandatory guidelines for Federal workplace drug testing programs at subpart B.2.2(23):

A higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

In addition, the individual with the authority to authorize collection under direct observation is specified in each agency's drug-free workplace plan

### SAMPLE SPLITTING

Secretary BOWEN. Uniformity and security is very important.

Senator MIKULSKI. Yes; because also I think, again to build employee confidence—one of the things we know, laboratory testing is not absolutely 100 percent and we want to ensure accuracy, and then also that it is the same sample that we are talking about.

Secretary BOWEN. Right.

### LABORATORY INSPECTIONS

Senator **Mikulski**. The last point I have on the guidelines, Doctor, is that the guidelines permit, but do not require, agencies to conduct a minimum number of unannounced laboratory inspections.

Why should we not require this? You know, if a lab knows an agency is going to come, they are going to be ready. But just as we random test employees, maybe we need to random test the labs.

Secretary **Bowen**. I will take that up with Dr. MacDonald.

[The information follows:]

### Random Test of Labs

The mandatory guidelines state in the preamble, the following: Several commentors indicated that laboratory inspections should be conducted unannounced and that union representatives should be permitted to accompany the inspection teams. The guidelines neither require nor prohibit unannounced inspections. They contemplate that agencies will, through their contract with a certified laboratory, specify the terms and conditions of inspections in accordance with the requirements in the guidelines. If individuals other than members of the inspection team were entitled to accompany the inspectors, it would significantly complicate coordination and conduct of the inspections. More importantly, we see additional participants in the inspection as inhibiting the laboratory's freedom to provide complete cooperation out of concern for protecting proprietary information. While some laboratories may be willing to provide escorted tours to union officials to illustrate the quality of their processes, the guidelines do not establish a right for union officials to participate in inspections incident to certification of laboratories under these guidelines (2.4(1) and 3.20).

### TESTING LABS

Senator **Mikulski**. Would you, please, because I think that is also an important part of the criteria and in building the confidence.

Secretary **Bowen**. I am sure many of those things will come out in some of the comments also.

Senator **Mikulski**. I am sure, and essentially I am bringing those to your attention now. And I must say, you have done a very good first step at developing very complex guidelines.

Secretary **Bowen**. Thank you.

### SOCIAL SECURITY STAFFING

Senator **Mikulski**. The second half of my question, though, is not as pleasant. Doctor, this then goes to the Social Security personnel issues raised by Chairman Chiles. He expressed concern about cuts among the employees at Social Security and I, too, am concerned.

Since 1981, the administration has cut 11,000 positions from Social Security. The 1989 budget proposes to cut another 10,000. On February 9, Senator Sarbanes and I wrote to you to ask to meet with you because we were concerned about two things:

One, that criteria would be developed for closing Social Security offices, that there be a uniform, consistent policy as to what criteria would be used for either closing or consolidation.

The second was we were very concerned about the morale situation in Social Security. As a physician, and an able physician I might add, you would be the first to say that there is a direct correlation between morale and productivity.

Your staff—first of all, we were told that you would not meet with us. We did not get an answer to the letter, and when we were called, your staff told us that Dorcas Hardy had everything under control.

Dr. Bowen, Ms. Hardy does not have everything under control. She really does not. And sir, if you would visit SSA in Woodlawn you would find that the morale at Social Security borders on that of a Superfund site.

### SOCIAL SECURITY SURVEY

I am really reaching out to you on this because I know you to be a man of compassion and commitment. I have no doubt about that. I have here—and this is not—I am standing because more of height than drama.

Secretary BOWEN. I share your concern. [Laughter.]

Senator MIKULSKI. Well, I will not ask you to stand on this.

But I have here, sir, 5,000 employees who have signed this, talking about the morale crisis at Social Security. Dorcas Hardy did commission a survey among her own senior managers, who validated these petitions recently. And let me just give you an opportunity to respond, but the kind of situation that goes on, last Tuesday there was a leak of heating oil at the Dickinson Building at Woodlawn.

Some 30 employees went to the hospital; 250 went to the Social Security nurses office. Fumes were so bad that people were vomiting. The building evacuation plan was not followed. The fire marshal had to order there to be an evacuation. There was a refusal to close the building.

Then the employees were required to go back to the building, and then for those who were ill and went home, they were told they had to take their annual or sick leave, and it was the building itself that made them sick.

Dr. Bowen, that is what we have at Social Security. We have an unresponsive head of the Social Security Administration, and you have a crisis of confidence out there, in addition to the employee cuts. You are cutting workers and now you have cut morale and we have cut productivity.

I am asking that you ask the HHS inspector general to investigate this incident at the Dickinson Building. But could you tell me now what you think you are going to do about this thing at Social Security? It is the biggest part of your budget and we have to get those Social Security checks out, and we cannot treat our workers that way.

Secretary BOWEN. Certainly I will look into the issues that you have brought up this morning. I am not aware that the morale is as bad as you have said. I think we have reasons to believe that the morale is not that bad. The service to the public has been excellent, and has been verified by the GAO in a recent report.

The morale. I think, is good enough to maintain the function quite well.

### SOCIAL SECURITY ADMINISTRATION SERVICE TO THE PUBLIC

For example, the waiting time in the Social Security offices is 7.2 minutes; and that is down from almost double that 2 years ago. The processing for Social Security numbers is down from 6 weeks to 11 days; and that is just over the past 3 or 4 years. The posted tax earnings is 5 months faster than just a few years ago and 2 months faster than this time last year.

I think another estimate of morale, or way of measuring morale, is the way in which individuals support the Combined Federal Campaign [CFC]. The Social Security offices reached 106 percent of their quota; which was a considerable raise over the last couple of years.

I do know that Commissioner Hardy conducted a survey. She is very concerned about this, and is now in the process of gathering the personnel leadership together to discuss this and to determine what can be done.

### ERROR RATES

Senator MIKULSKI. Doctor, we could talk about performance and productivity. I know the chairman will raise questions with you, the same as he did with Ms. Hardy at the SSA budget hearing.

But the GAO information also says that Social Security's error rate for processing retirement claims has jumped by one-third from 1985 to 1987. The total errors from old age and survivors insurance, the error rate alone has grown to 31.5 percent, up 23 percent since 1985, and we could get into that.

The chairman at our hearing also said that Ms. Hardy was not even taking into consideration busy signals and a variety of other things. What I am asking you to do, Dr. Bowen—and I am not going to tie up this committee—No. 1, I want you to read Hardy's own survey of what her own managers said about the situation there.

Second, I would ask you to have your inspector general take a look into the situation that we talked about at the Dickinson Building. I would be the first to tell you, this information comes from employees. I believe in second opinions, Dr. Bowen. I believe in second opinions, and that is why I would like for you to take a look at this.

In your capacity as head of HHS, I know you want to do a good job, and in many ways you have been very responsive and I am most appreciative of this. This could be a significant contribution if you could take the leadership and not just listen to what Ms. Hardy tells you, but listen to what the workers are telling you, the GAO is telling you, and your inspector general will tell you about the conditions at Woodlawn.

And it would be, I think, very important to the delivery of an important service.

Mr. Chairman, I think we could go on about it, but I do not want to take the time of the subcommittee. You have been very generous.

Senator CHILES. I thank you.

Senator Domenici.

Senator DOMENICI. I yield to Senator Specter.

Senator SPECTER. Thank you, Mr. Chairman. Thank you, Senator Domenici.

### ACQUIRED IMMUNE DEFICIENCY SYNDROME TRANSMISSION

In the few moments allotted to me this morning, I would like to broach two subjects with you rather briefly: one, the subject of AIDS and two the subject of rehabilitation on drug abuse.

Yesterday, the Senate debated extensively AIDS legislation, and I do not think there was too much material in our debate yesterday for a new chapter in "Profiles of Courage" as we went through that issue. There was a great deal of concern about dealing with AIDS, but in the process we do not want to promote drug use or homosexuality. But we are very interested in trying to find ways to limit the transmission of AIDS.

### PROVISION OF CLEAN NEEDLES TO DRUG USERS

I would like to ask you about one of the issues which we discussed, and that is the substitution of needles, where the program has been advocated that clean needles ought to be made available to drug users, as opposed to having them use old needles where AIDS may be transmitted.

And let me start with the question as to whether you think that making clean needles available would stimulate drug use above and beyond what would happen if clean needles were not made available?

Secretary BOWEN. I do not think anyone can really answer that question, but it would be my judgment that it certainly would not be a deterrent. I personally would not approve of having a program of furnishing clean needles.

However, I would not disapprove of a pilot project to get some understanding of what the outcome would really be. I think they would go ahead and reuse the needle. It is just another source of more needles.

Senator SPECTER. So you would favor a pilot project, but not a program?

Secretary BOWEN. I did not say I would favor it. I said I would not try to block any program.

Senator SPECTER. You would not favor it, but you would not try to block. That sounds like our debate last night.

Secretary BOWEN. That is the situation.

Senator SPECTER. Not favor, but not try to block.

Well, let us examine the question to see where we may be heading. I quite agree with you that nobody knows the answer.

But to focus on one question, it would be if you have a drug addict and he has got a needle, an old needle that has been used perhaps by many drug addicts, perhaps by some who have AIDS. Now, the question is, he has an opportunity to get a clean needle; is he more likely to use drugs if he has an option of a clean needle than if he has this old needle?

Would he be discouraged from using drugs with the old needle because of his concern about getting AIDS, and would he be more likely to use drugs if he has a clean needle? Now, that is a hard question, but you are the Secretary of Health and Human Services.

We Senators have some experience. I have been a district attorney before being a Senator. But what is your judgment on that question?

Secretary BOWEN. An addict could care less about AIDS, dirty needles, or anything else. When he wants a fix, he wants it now. So I just cannot see that the addict is going to be real faithful about turning in a needle and getting a clean one. I think that if it is convenient he might do it. If it is not convenient, he will use the dirty needle. The answer is to try to get these people into treatment.

Senator SPECTER. All right. So as to the needle issue, he is going to use a needle whether it is a clean needle or a dirty needle. So the availability of a clean needle is not likely to make him more likely to use drugs?

Secretary BOWEN. I do not think that would make any difference. When he used that clean needle once, there would have been that much less of a chance, of getting AIDS, for that one particular time.

Senator SPECTER. But then the question is whether he would have enough interest to substitute a clean needle for a dirty needle. But if you could get him to substitute it, he is not likely to be any more of a drug user one way or another, and he is less likely to transmit AIDS if he has a clean needle.

Secretary BOWEN. Right.

### ACQUIRED IMMUNE DEFICIENCY SYNDROME PILOT PROGRAM

Senator SPECTER. And you would not block a pilot program to see if this could be an effective way of stopping the transmission of AIDS, but you would not be an advocate for it either?

Secretary BOWEN. Right.

Senator SPECTER. Well then, I guess we have to find someone who is willing to be an advocate if we are going to have a pilot project.

Dr. Koop has commented about this subject and has taken pretty much the position that you have. He would not block one, either. So the issue is whether or not we can structure a pilot project which will not encourage drug use, but which will give us some insight as to how we might restrain the transmission of AIDS.

Secretary BOWEN. I think there are some pilot projects going on now, in a few States or cities. I think we can learn some lessons from what they have done.

Senator SPECTER. Are those being studied and observed by your Department?

Secretary BOWEN. I am sure they are, but I do not know by whom.

Senator SPECTER. Well, if you could supplement that answer for the record and tell us the specifics on what is going on, what the preliminary findings have been if there have been any findings, and what you intend to do in pursuance of that.

Secretary BOWEN. Yes, sir.

[The information follows:]

### THE EFFECTIVENESS OF DRUG ABUSE TREATMENT

Drug abuse treatment is effective in reducing intravenous drug abuse. For intravenous drug abusers, two treatment modalities—methadone treatment and therapeutic community treatment—have been the most widely used and provide the clearest evidence of treatment effectiveness.

Intravenous drug abusers experience immediate and dramatic reductions in drug use following enrollment in methadone treatment, and these reductions continue throughout treatment. A number of studies have illustrated these reductions, with an average of 75 percent of clients using no illicit opiates while in treatment. A large-scale study of 44,000 addicts enrolled in 52 treatment programs found that average opiate use by clients in methadone treatment was reduced from 30 days per month to 1 to 2 days per month. Furthermore, the longer addicts remain in methadone treatment, the more effective it is in reducing illicit opiate use. In one recent study, opiate drug use decreased from 100 percent of addicts entering treatment to 23 percent of those in treatment 1 to 4 years and 8 percent of those in treatment for 5 or more years. Since opiate addiction is a chronic disorder, addicts need to be maintained on methadone until more normal living patterns are established.

The second treatment modality is the therapeutic community. Therapeutic communities are long-term residential treatment facilities that provide highly structured environments in which clients learn adaptive behavior patterns. Like methadone treatment, therapeutic community treatment also results in substantial reductions in opiate use. In one large-scale study of opiate addicts, daily opiate use was reduced to 39 percent during a 1-year posttreatment followup. In another large-scale study of opiate abusers who had used weekly or more frequently prior to treatment, 54 percent reported no opiate use and 19 percent reported less use in the year following treatment. As with methadone treatment, favorble outcome with therapeutic community treatment depends on the ability to retain clients in treatment. One study found that fewer than 5 percent of program graduates reported opiate use during a 5-year followup period, compared with 95 percent who reported opiate use prior to treatment. In another study of addicts who used opioids daily prior to treatment, only 29 percent of those who remained in treatment for longer than 90 days used opioids daily following treatment, compared with 52 percent of those who were in treatment fewer than 90 days.

The research studies cited above demonstrate that methadone and therapeutic community treatments are effective in not only reducing illicit opiate use, but also in reducing other drug use, increasing employment, improving psychological adjustment, and decreasing criminality.

However, while methadone and therapeutic community treatments are effective for those who complete treatment, retention of clients in treatment is a significant problem. In methadone treatment, favorble outcome depends in large part on the ability of programs to retain clients until they have satisfactorily completed treatment. For clients who drop out of treatment prematurely, most eventually relapse to opiate use. Rates of abstinence following treatment, however, are high for those patients who satisfactorily complete treatment. For example, in a study that followed heroin addicts for as long as 6 years after methadone treatment, 83 percent of those who terminated with staff approval (that is, met discharge criteria) were opiate-free, compared to only 21 and 23 percent who terminated prematurely. A high percentage of intravenous drug abusers drop out of treatment prematurely. For example, one study of methadone treatment found that only 17 percent of clients leaving treatment left with staff approval. A study of seven therapeutic communities in six States found that 12-month retention rates averaged 12 percent. The problem of retention reflects the chronic and severe nature of drug dependence. While attrition from treatment is a concern, many of those who drop out subseqnelty return to treatment. In fact, approximately 80 percent of heroin addicts admitted to drug abuse treatment have previously been in treatment. Fortunately, many of these intravenous drug abusers achieve long-term abstinence following several treatment episodes.

An important corollary to the reduction of illicit opiate abuse, is that these treatment modalities can be expected to have a significant impact on efforts to reduce the transmission of AIDS among intravenous drug abusers and their sexual partners. By reducing intravenous drug abuse, these treatments reduce needle sharing which is the primary way in which AIDS is spread in this population. One study in New York City found lower rates of HIV infection—23 percent—among heroin addicts in methadone maintenance treatment programs than rates found 47 percent among those who were not in treatment. In addition, the lowest infection rates were among those who had been in treatment the longest. A study of methadone clients in Italy similarly found that infection rates among recent admissions to treatment were substantially higher than among clients who had been in treatment for some time.

## DRUG REHABILITATION

Senator SPECTER. Let me turn for just a moment to the issue of rehabilitation, which you had already said you thought is really a preferable answer and I quite agree with you. If we could find ways to take people off of drug use, that is the best yet. Then they do not have to deal with sterilized needles or used needles.

There has been a lot of work done in the field of rehabilitation, trying to take people out of the drug cycle, for a long period of time. I recollect more than 20 years ago seeing the results of Daytop Village, which was one of the original groups in New York working on this program.

I would be interested to know, Mr. Secretary, if there have been any studies which shed any light on what kind of rehabilitation of drug users is effective, any studies as to how many people have been taken off the drug habit with the variety of rehabilitation processes, so that we have some insights as to how to apply the limited funding we have for this important subject?

Secretary BOWEN. Well, the recidivism rate is fairly high. I do not recall the exact number. We can get it for you. The recidivism occurs most often in the first 90 days, so it means to me that the followup after release from treatment is inadequate. They should be followed for a longer period of time.

Senator SPECTER. My question, Dr. Bowen, is what is the best way to approach rehabilitation? There are many different approaches. Have we studied the varieties of approaches to try to make an evaluation as to which is the most effective?

Secretary BOWEN. Our National Institute of Drug Abuse, or NIDA, is conducting studies now on the best means of treatment, rehabilitation, and the length of time that it would take.

It is my personal judgment that, to be effective, the addict must be kept in an institution totally away from drugs. If you are going to be serious about treating these people, you essentially have to put them in a place and keep them there until they are totally over the desire for more drugs. Then they need to have some followup after release for a long enough period of time to be certain that they will not fall back into their old habits.

Senator SPECTER. How long is the minimum necessary on that kind of inpatient treatment?

Secretary BOWEN. It would vary by individual and by drug.

## EVALUATION OF DRUG TREATMENTS

Senator SPECTER. Dr. Bowen, I do not want to take up any more time because others are waiting to question. I would appreciate it and I think it would be very useful to the subcommittee if you could give us for the record an evaluation to the extent that one has been made of the variety of treatments which are in the field today.

[The information follows:]

### NEEDLE EXCHANGE PROGRAMS TO PREVENT AIDS

Since AIDS is spread among intravenous drug abusers through the shared use of contaminated needles and syringes, a number of individuals and groups have suggested that sterile needles should be made readily available to intravenous drug abusers. While not advocating widespread implementation of such a program, the National Academy of Sciences has suggested that the impact of making needles readily available should be assessed.

It is the Department position that insufficient data is available regarding the effects of a free needle program to support implementation at this time. Such a program may or may not reduce needle sharing, since the act of sharing a needle has symbolic as well as utilitarian significance within the drug abuse subculture. Of particular concern is the possibility that readily available needles may facilitate the initiation of intravenous drug use by nonintravenous abusers.

Another approach to reducing the transmission of HIV among intravenous drug abusers is to inform abusers about steps they can take to sterilize their injection equipment.

The National Institute on Drug Abuse [NIDA] is exploring issues related to the availability of needles and needle sterilization. Regarding free needles, however, we believe that the possible negative consequences are sufficient as to require caution. Needle exchange programs exist in several countries (Netherlands, United Kingdom, Sweden) and are being implemented in several sites in the United States. NIDA will monitor data coming from these programs to determine their effectiveness.

## DRUG TREATMENTS

Senator SPECTER. There must be many, many varieties of drug treatments, and they go on inpatient and outpatient. They turn on how long a period of time both varieties are tried.

We have just taken a step, with the leadership of Senator Chiles, Senator Domenici, and Senator Murkowski and many of us, on putting up a lot of money for the drug issue. We put up $1.8 million in October 1986, and we are really floundering as to what the results have been.

We are now talking about putting up more than $2 billion again. I have a sense that we would be well advised to put extra resources on the demand side, on education, and on rehabilitation, as opposed to the very heavy emphasis on the supply side.

We are putting tremendous sums of money on the supply, with relatively little to show for it. Entire governments in South America are subverted by the dollars. So maybe we would have better luck in the overall approach of putting more funding on the demand side.

But in order to make that evaluation, it would be very useful for us to know how programs like Daytop Village, Codenzia House, and Outgrow have fared in taking people off of the drug cycle, and what we might realistically expect if we put *x* dollars into rehabilitation, if some programs have really been successful, so that we might apply more of our resources in that line.

Secretary BOWEN. Sir, now you are speaking my language. This is what I have been preaching here for several years now; that as long as there is a demand there is going to be a supply.

We need to exert greater efforts to reduce demand, and that is going to take perhaps many years to get accomplished. We have got to get people at the local and community level involved; the teachers, preachers, the parents and the grandparents. The leaders in each community must establish their own programs.

We have about 1.4 million intravenous drug users who really are in need of treatment, and there are many thousands of other types of drug users that need treatment too. We are only able to take care of about 140,000 at any one time.

Treatment slots are short. In 1987, the States applied for money, but they were unable to use, I believe, more than about 40 percent of it. The 1988 money is still available.

There are several reasons for that. The money that came in 1987, came fast and in one lump sum, and the States were not adequately prepared to utilize it. Many of them had to pass appropriations in their own legislatures to use it. That would account for some of the delay.

But one of the biggest delays was the fact that people say, yes, I am for treatment, but do not put a treatment center in my backyard. So they go to court to prevent getting a treatment center in the proper place.

## EVALUATION AND REHABILITATION

Senator SPECTER. Dr. Bowen, my final comment is that I believe you would find great receptivity in the Congress, the Senate and the House, on putting up these funds for education, rehabilitation, if we had some solid evidence of the success of the approach.

There have been programs in the field for a long, long time. As I say, I went in 1968, some 20 years ago, to Swan Lake, Daytop Village, on a marathon, participated in some of the programs as an observer. I was not a user, obviously. I was district attorney of Philadelphia at the time.

I went through an extraordinary experience on a marathon session that started at midnight after a full day tramping around the grounds, went 24 hours; a few hours of sleep, another 16 hours.

And this is an approach which they used there. We then brought that program to Pennsylvania in Codenzia House. And I have never seen any comprehensive body of statistics as to what the results have been.

And of course, that is only one approach. There are many, many approaches—inpatient, outpatient. And if you could provide statistics which would demonstrate the effectiveness of such programs, I think there is a great inclination to pay for it if we would know what we are getting in value for the dollar.

Secretary BOWEN. The voluntary commitment is not going to work. It will have to be a mandatory commitment and they will have to be kept until they are cleared.

I would mention that NIDA this next year has $2.3 million available for treatment outcome research. So we are pursuing that.

Senator SPECTER. Thank you very much.

Thank you, Mr. Chairman.

## FEDERAL FUNDING

Senator CHILES. Mr. Secretary, along that line, your answer to the question of needles or not I think was a very good answer: We have got to get these people into treatment. We are talking about that.

And yet, the Federal Government's commitment to treatment now is about 18 percent, the rest falling on the States or someone else. Given that this is a Federal problem, and I think it definitely is—the States cannot keep drugs from coming in when they are coming out of Colombia and Bolivia, the high seas and every other way. And the States cannot deal with the illegal aliens, the Haitians, the Jamaicans, the gangs that are selling these drugs.

Most of this is sort of on the Federal Government's platter. And yet, we are seeing this 18 percent of the total.

How can the States be expected to bear this burden of expanded costs? Should not the Federal Government be looking at this, in just the same way that we are trying to look at increasing our enforcement?

Secretary BOWEN. The Federal Government has the major responsibility when it comes to the supply, but when it comes to demand, that is a combination of Federal, State, and local government, and even local communities.

As far as the supply goes, the States get some of the money. In fact I think they receive a good share of the money that is seized as a result of grabbing the individuals who are bringing the dope into the country.

Senator CHILES. They are beginning to share a small fraction, but that is a fraction of what the Federal Government is seizing, and our total seizures in relation to what our treatment costs will be are still small.

Secretary BOWEN. We are far behind

## ACQUIRED IMMUNE DEFICIENCY SYNDROME MAILER

Senator CHILES. Yesterday I met with Dr. Noble at CDC to review the every household AIDS mailer that will go out to every American household at the end of May. We put language in last year's bill to require the mailer to go out. We had to put bill language in that CDC be required to clear the content of the mailer with everyone in the administration.

We had to do this because in our first effort, we said that this should be done and we put the money in so it could be done, but it did not happen because there was a debate over the contents. I think that—I know what I wanted, and I think other Members of the Congress as well wanted a mailer that put out the facts.

I know you have seen the mailer. What is your opinion? Do you believe that CDC has produced a good factual document now?

Secretary BOWEN. Well, obviously I am prejudiced when I say this. I think it is an excellent document. We have involved the entire HHS as far as the Public Health Service goes, and we have had our experts in AIDS critique it.

We have had some sampling done by the public to determine what they needed, felt they needed to know, and what they wanted to know. They have also seen the final report, and it is almost unanimous that it is an excellent piece of material.

It is factual, straightforward language, easy to understand; written so that about a 12- or 13-year-old can understand it. It is not in college language. There are 110 million of the mailers that will be ready to go. The mailing will occur some time between the middle of May and the last of June.

This is a tremendous undertaking. I saw some information concerning the tons of ink it took to print them.

Senator CHILES. I understand we have boxcars full of these.

Secretary BOWEN. Right.

Senator CHILES. I want to say, Mr. Secretary, I want to say I am pleased with it, too. I felt it was very factual. I think it is a hard-hitting document. I know it will not please everybody.

But I want to congratulate you and the people at the Centers for Disease Control, Dr. Koop and everyone else that worked on that. I think the message that it says is very plain and very clear: The best way not to get AIDS is not to participate in the sexual activity or in the IV drug use.

But it also goes further to say, if they are not going to heed that warning, what kind of precautions they should take. And I think it also goes a long ways to try to help dispel some fears that are out there, that we know that are out there, that you cannot catch AIDS from eating in a restaurant, you cannot catch AIDS from sitting on a toilet seat, you cannot catch AIDS from a casual contact or being in a classroom with someone that has it.

But it takes the exchange of body fluids that comes from a sexual activity or comes from the IV needle. It is transmitted, as we know, tragically, from a pregnant mother who is a carrier, to her child. And of course, we saw some in earlier days transmission by blood transfusions.

Hopefully, we are now screening the blood, and we have tests that will prevent that.

NEGATIVE REACTIONS TO ACQUIRED IMMUNE DEFICIENCY SYNDROME MAILER

I think the document makes all of this very clear. I understand that you are starting your briefing of other people soon. And there may be some outcry, because there will be those that, again, always hate to talk about this kind of subject.

I hate to do it, too. I hate the idea that we are having to send this to every household in this country. But at the same time, I hate that it is a year later than it ought to be because, with the kind of infection and the disease that we have no cure for, we have got to get this information out.

And I hope every household that gets it will discuss it in their household, they will talk to their children about it. It is going to need to be talked about.

We have got to—education is the only way now that we can do something to prevent this disease from spreading. It is the only way because we have no cure.

Secretary BOWEN. Yes; I regret too that it is a year later, but I would have to admit that the pamphlet is better than it would have been a year ago. I am pleased with it.

It tells how to get it. It tells how you do not get AIDS. And it also stresses, it is not who you are, but it is what you do. I think that is an important message.

Senator CHILES. I think so.

My understanding is when England sent this information out, they found they had a tremendous number of telephone inquiries, of people wanting to ask additional questions. And my understanding is you are beginning to prepare for that, and you are going to need to reprogram some funds.

Do you have that reprogram request ready? I trust we are going to get a chance to see this.

Secretary BOWEN. Yes; it is being prepared. We regret what happened before, but we were under pressure also, as you well know.

I am ready for some nasty reactions and letters, and I am considering getting an asbestos suit to wear for a week or so. I think it is going to be accepted by a vast majority of the people.

Senator DOMENICI. Mr. Chairman, I do not want to interrupt you. I want you to continue, and I want to compliment you on your remarks.

I think the Secretary needs remarks like yours, the chairman of this committee, and the chairman of the Budget Committee, just made. I am hopeful that our colleagues, the U.S. Senate to a person, will help take the heat, because there will be a lot of it.

I do not know any other way to approach AIDS. You cannot talk about this kind of subject without offending someone. But I think the sooner we get the truth out, the better. I understand the brochures' format and something about its content, and I join in the compliment that the chairman has given to you and to the Department.

I am hopeful that the public's reaction will not be such that we will cease our efforts to be as honest and as forthright to the American people as we can in terms of what we do not know and what we do know about AIDS, and what we ought to be doing and what we ought not to be doing.

And I want to join in the compliment to you, Mr. Secretary, but also compliment our chairman for his words, which I think were very forthright. As he indicated, it is a lot easier not to be talking about this kind of subject. It is a lot easier to not have to mail this information to American households, either. We do not do that very often in this country.

Secretary BOWEN. It is a first.

Senator DOMENICI. And that is not our style. We want to be free. We do not want anyone telling us what to do. But this is not ordering anyone to do anything, as I understand it. We are still free to make our own choices. But it surely ought to make some people stop and think. And I join in the compliments to you.

Secretary BOWEN. Thank you. Your comments help considerably.

I think it is $17 million well spent. That is the total cost of the mailing.

Senator CHILES. Well, we want to help insulate your asbestos suit a little bit.

### HOMELESS FUNDING

Doctor, your Department has put out material suggesting that you are proposing a 7-percent increase in funding for the homeless over the 1988 level. Those totals include funds from regular ongoing programs, like Medicaid, which serve the homeless as part of their eligible client pool.

When you look at the funding specifically targeted to the homeless by the Stewart B. McKinney Act, the 1989 total actually drops by almost 14 percent. Given these numbers, do we not have to question the sincerity of the administration's rhetoric about compassion for the homeless?

Secretary BOWEN. My data show that we are requesting $93 million in 1989, which is a 7-percent increase over 1988 of $87 million. In 1987, it was $158 million, but that was due to the large initial congressional appropriation for a quick expansion of the program.

The $93 million request includes $52 million for mental health and primary health care services, and has $26 million in OHDS for our runaway youth, who certainly are homeless. Medicaid has $15 million for clinical services outside of the traditional clinical setting, in mobile vans and so forth. We are trying to take the program directly to the homeless.

I don't think we are neglecting them.

Senator CHILES. As I look at the figures under the McKinney Act program, I see the family support for 1989. There is no proposal there. Human development services, there is no proposal.

So under those programs, it goes from $44 million to $38 million in those particular programs.

Secretary **Bowen**. The McKinney Act is only a portion of the total that we are spending. I have data here prepared by our budget people.

Senator **Chiles**. I know it is a portion and part of the continuing programs, but that is the area that we specifically tried to identify in the homeless.

### REFUGEE ADMISSIONS

Turning now to refugee admissions, there appears to be a good possibility that in 1989 the refugee population entering the country could be as much as 47,500 higher than the 51,000 level assumed in your budget request. First of all, your budget does not account for 17,500 refugees in the official State Department ceiling estimate of 68,500.

Second, it does not support the 15,000 additional Armenians and other East Europeans likely to be admitted on an emergency basis later this year.

And third, it does not accommodate a possible 15,000 increase in Amerasians, the offspring of our servicemen in Vietnam, who would be eligible for refugee assistance under a provision added to the 1988 continuing resolution.

Is this assessment an accurate update of the events that have developed since your fiscal year 1989 refugee budget was formulated?

Secretary **Bowen**. Sir, if I could ask Mr. Stanton to answer. That comes under his department.

Senator **Chiles**. Yes.

Mr. **Stanton**. Mr. Chairman, we did predicate our budget on 51,000 new applicants or new admittants. We now have data that suggests the number would be 68,500 new admittants to this country, can be expected in fiscal year 1989. An additional 15,000 Armenians in fiscal year 1988 and perhaps as many as 30,000 Amerasians by fiscal year 1990. We have not budgeted for these new, unexpected groups of people.

Senator **Chiles**. Will you seek a budget amendment from OMB to cover the extra refugee resettlement costs?

Mr. **Stanton**. That is currently under discussion. The Secretary and OMB will make that judgment.

Senator **Chiles**. I do not see how—do you want to take that under advisement and give me a decision right now, Mr. Secretary?

Mr. **Stanton**. Mr. Chairman, there are some later developments with respect to the Armenians admittance, but I am not exactly sure those admission numbers are final at this point. They might be, they might not be, Mr. Chairman.

### BURDEN ON STATES

Senator **Chiles**. What I know from what has happened time after time, when this happens they are going to be here, and they are going to be at the States' doorsteps, and they are going to be at Jackson Memorial Hospital seeking assistance in Miami, and wherever the hospital is in Albuquerque, and everyplace else.

And the burden then falls on the State and local governments. And they are taking an unfair burden now. This is totally Federal policy. This is not anything that the States have to do, and it is just plain not fair. It is our policy or lack of policy, the Federal Government, that sets up this refugee assistance, and we should not make the States always be trying to play catchup and never get a fair shake on this.

Do you think it is fair to make the States pay for the refugee resettlement costs as a result of Federal actions?

Secretary Bowen. No; it falls unequally on States. I suspect Florida, Texas, and California will have the greatest burden.

Senator Chiles. Absolutely. I can tell you something about how it falls unequally on States from the burden that my State has had over the different waves of refugees. We are constantly trying to convince the Federal Government to try to do something and to get on top of this.

I hope you will ask for a supplemental here. I think this is something that is only fair to do and not have this go on the States.

### HEAD START

You propose freezing Head Start spending at last year's level, which is $48 million below the current level the Congressional Budget Office says is needed to maintain current services.

How can we realistically expect to serve the same number of children without a reduction in service quality, with no more money than last year in this program?

Secretary Bowen. This falls under Ms. Olson's department. She will respond.

Ms. Olson. Senator, the Head Start received a $75 million increase last year, and we are utilizing that money to provide increased salaries, and increased contact time for the students. Over one-half the States also put money of their own into the Head Start Program.

We believe that will be able to serve the same number of children without a reduction in service.

Senator Chiles. What percent of the children that are currently eligible are served by Head Start?

Ms. Olson. Between 16 and 20 percent of the eligible children are served.

Senator Chiles. And we are not providing actually as much money as we did last year, because we know inflation has gone up. We know there are additional costs.

Ms. Olson. We have level funding proposed for next year.

Senator Chiles. Level funding. But that is not enough to take care of the additional cost.

Ms. Olson. We believe we will be able to serve the same number of children with the same funding level.

Senator Chiles. If we are right and we serve the same number of children, we are not going to serve them as well if the costs have gone up. Something has got to give with that, and when we are only funding 16 to 20 percent that is a tough one.

### OLDER AMERICANS

Your budget would freeze all of the programs authorized under the Older Americans Act at the 1988 levels. Again, how can we justify not even maintaining the current services, given the rapid expansion of the elderly population and the importance of these services to help keep older Americans out of institutional care?

Secretary BOWEN. It is really a question of priorities. We prepared our budget after consideration of the bipartisan budget summit agreement, and we had to make some tough choices. This just happened to be the way the priorities fell.

Mr. STANTON. Mr. Chairman, would you be offended if I left? I have a plane to catch. My deputy will remain here with you to answer any questions?

Senator CHILES. No one has ever worried before whether I was offended or not. You are free to leave.

Mr. STANTON. Thank you, Mr. Chairman. Thank you, Mr. Secretary.

### LOW INCOME HOME ENERGY ASSISTANCE

Senator CHILES. Mr. Secretary, I know you have got a problem, too. Let me just ask you, your budget justification indicates, of the $1.7 billion in oil overcharge funds so far designated by the States, only $275 million or 16 percent has been designated for the low income home energy assistance program.

Why are the States earmarking such a small percentage of all oil overcharge funds for this low income home energy assistance program?

Mr. STURMAN. That is a hard question to answer.

Senator CHILES. This comes from your budget justification.

Mr. STURMAN. Our justification says that States have designated LIHEAP as the use for $275 million and there is approximately $1.3 billion in undistributed oil overcharge and stripper well funds.

Senator CHILES. Of that $1.3 billion, how much do you reasonably expect?

Mr. STURMAN. The States have the option, Mr. Chairman, of designating all of that for low income home energy assistance purposes if they so choose. Some States have 4 or 5 year plans that show different data. They have the option to change those plans, depending upon local financing circumstances.

It is completely the option of the States as to which one of the four or five HHS and Energy Department programs they choose to designate.

Senator CHILES. Well, based on history, how much do you expect they will use of this $1.3 billion for this program?

Mr. STURMAN. I think our projections would be dependent upon how the States choose to prioritize the funds.

The GAO reports that only 12 percent of the recent stripper oil overcharge distributions have been used for the low income home energy assistance. So it appears that States are using these funds for roads and potholes.

Senator DOMENICI. And bridges.

Mr. STURMAN. The States have the option of choosing to spend it in different ways. I think there is evidence, for example, in the Northeast States particularly Massachusetts—which when a lower funding level was enacted for 1988, the State made up the difference by substituting its own funds and increasing the allocation for the oil overcharge stripper well funds.

They have the option of changing their priorities.

Senator CHILES. According to a survey sponsored by the National Consumer Law Center and the National Energy Directors Association, three-quarters of the States have either cut the amount of benefits or curtailed the amount of households served by the low income home energy assistance program.

What information do you have about the impact of the 1988 appropriation cuts on beneficiaries of the low income home energy assistance program?

Mr. STURMAN. I do not have any data with me. We will provide this data for the record.

Senator CHILES. I would like to have that.

[The information follows:]

### LIHEAP—IMPACT OF 1988 APPROPRIATION CUTS

The Federal appropriation for LIHEAP was reduced by $185 million from fiscal year 1986 to fiscal year 1987. However, in fiscal year 1987, 30 States channeled $186,710,952 in oil overcharge settlement funds into their LIHEAP programs, resulting in approximately the same level of total funds available in fiscal year 1986 ($2,135,999,971) as fiscal year 1987 ($2,119,458,365). Nationally, the same number of households were served by heating assistance in fiscal year 1987 as were served in fiscal year 1986. In both years, about 6.4 million households received heating assistance and about 6.8 million households received help with heating costs through heating or winter crisis assistance. The average benefit for heating assistance was $213 in fiscal year 1986 and $205 in fiscal year 1987.

In fiscal year 1988, the States allocation of $416 million in oil overcharge funds to their LIHEAP programs offset one-half of the $290 million reduction in Federal appropriations for LIHEAP from the previous fiscal year. Nationally, 6.3 million households were assisted with their heating costs in fiscal year 1988, as compared to 6.8 million households in fiscal year 1987. The 500,000 reduction in households assisted with heating costs represents a 7-percent reduction from the previous fiscal year. The average benefit for heating costs declined from $205 in fiscal year 1987 to $199 in fiscal year 1988. The $6 difference in average benefits for heating assistance represents a 3-percent reduction from the previous fiscal year.

Nationally, the results of the Office of Energy Assistance winter phone survey indicate the States estimate that they will reduce the proportion they transfer to other block grants or carry over to the next fiscal year in order to increase the proportion of their LIHEAP allocation expended on heating and crisis assistance. For example, in fiscal year 1987, 33 States transferred $93 million of LIHEAP funds to other block grants, 9 percent of their national allotment. In fiscal year 1988, 27 States transferred $56 million of LIHEAP funds to other block grants, 4 percent of national allotment.

### LOW-INCOME POPULATION

Senator CHILES. What impact would your proposed 20-percent reduction in 1989 have on the low-income population?

Mr. STURMAN. We will provide that also.

[The information follows:]

### LIHEAP—FISCAL YEAR 1989 IMPACT ON LOW-INCOME POPULATION

Because LIHEAP is a block grant which affords the grantees flexibility in designing their energy assistance programs, we are unable to estimate the impact of a reduction in Federal appropriations on LIHEAP eligible households until the States design their fiscal year 1989 LIHEAP Program. Under a block grant, there is no direct correlation between reductions in Federal appropriations and households served. The LIHEAP grantees may supplement their Federal appropriation with State or oil overcharge moneys, not exercise their option to transfer funds out of LIHEAP into other block grants, eliminate a service component such as cooling or weatherization or reduce the size of the benefit provided. Because of the flexibility of the block grant, we are unable to estimate the number of households that will be served, nor the average benefit level under any level of Federal appropriations until each State decides on the design of their LIHEAP Program for that fiscal year.

### LOWER FEDERAL APPROPRIATIONS

Mr. STURMAN. I would again stress the fact that, with lower Federal appropriations, the States have the option of increasing their appropriations, as well as retargeting the stripper well and oil overcharge funds.

Senator CHILES. Mr. Secretary, I know you have a problem, so we will submit the rest of our questions for the record in writing.

Excuse me. Do you have a few?

### DRUG DEMAND

Senator DOMENICI. Yes; I have some questions, Mr. Chairman.

Let me join in with reference to the drug problem in this country. You answered questions from the Senator from Pennsylvania indicating, as I understand it, that he was singing your tune when he talked about the demand side. Let me just suggest, Mr. Secretary, that there are many of us who believe that to be true.

We know that we have to somehow or other talk our young people and others into quitting the use of hard drugs. I just want to join in suggesting that, wherever you can, you help us in that regard.

It is easier to address the supply side in terms of objective results when we can see numbers of arrests, incarcerations, and imprisonments. Some of us want to continue with that in a forceable way.

But it seems to us that for every one we put in jail and get off the streets as a major peddler, that one or two more will replace them so long as the demand is out there. I personally think it is not a misnomer to call this a war, because I believe it is serious enough that our very survival as a society might be at stake.

We may lose a substantial portion of a generation. And if we keep doing it for two or three generations, the toll on this country will be immeasurable.

We seem to be very willing to spend money, but we need to have a concerted effort against drug use that uses every tool at our disposal, from the educators to the media. And I think you left the media out of your statement. I think you would include it—advertising, mass media, the written media in promoting the very best on the positive side against drug use.

So I want to say that, while we are very willing up here to expand the programs, we need every bit of advice we can and every bit of evidence of success we can expand upon. I personally believe we are not going to succeed—I know this is a wild statement—but I do not think we are going to succeed until we remove the users from the streets.

I think it is going to have to happen sooner or later. I have read with some interest that Japan had a major drug problem a few decades ago, and what they did, literally, was to remove the users from the streets. They put them in hospitals all over the country, and that is where they stayed until the authorities thought they should be released.

Obviously, that is very difficult to do in America, and it may not work. But something very drastic is going to have to happen sooner or later, in my humble opinion.

Secretary Bowen. I would agree with you 100 percent, and simply state that the certainty of getting caught or the certainty of punishment would be one of the biggest deterrents; this has to start with the user. I think we must have to have a zero tolerance for the use of drugs.

Senator Domenici. I also want to add, for those who may think this kind of attitude is directed only at those who are poor or that live in our slums, that as far as this Senator is concerned, I would expand the confiscation law for this country. If we have wealthy people using hard drugs on their premises and that is provable, as far as this Senator is concerned, I would be for forfeiting their property rights to that facility, whether it is a condominium or a house. Put the proceeds from such confiscations into a fund to solve the drug problem. That may not be going too far when you consider the seriousness of the drug problem.

## HOMELESS PROGRAMS

Now, Mr. Secretary, I want to move to two other areas, and urge that you help Congress. The first is homelessness. One of our problems is that when we pass a bill that addresses homelessness, we have the natural tendency to spread the program among Federal departments. That is the way we do things.

You and your Department have responsibility for part of the homelessness issue. The National Institute of Mental Health has part, and HUD has another part.

I urge that you take the lead in evaluating the effectiveness of our homelessness programs, because we are getting piecemeal information, when we know that it has to be a coordinated and comprehensive program.

We cannot properly do our job if we get a few results from NIMH on the mentally ill in the streets, some from HUD on transitional housing, and some from you on other aspects of the homelessness problem. We need somebody coordinating an analysis of this major program and how the $800 million that we put into the field is being used.

As we draft the successive authorization bill, we hope to correct some of our own errors. We certainly are not the last word at drafting legislation to launch a successful program of this type. I personally am very concerned about the grant program. We have grants going to the States, some going to communities, some going to applicants who succeed with a program. Frankly, I think we need to make more sense out of the grant program for homelessness.

I urge you to use your position and take the lead in coordinating and advising us on how to better run a program like this.

Do you have any thoughts on that issue?

Secretary BOWEN. We transferred the functions of the Federal interagency task force to the new interagency council, as was required by Public Law 100–77. I will serve as the vice chairman of this interagency council. Secretary Pierce, of Housing and Urban Development, will serve as the chairman.

We have had a couple of meetings already, and the emphasis is on doing just what you said. We realize the program is fragmented, and we are going to try to pull it together and see if we can make it more effective.

Senator DOMENICI. I know we are running out of time. I was going to talk about Social Security, but I think we have talked about it enough. We are concerned in our State, too, about the morale problem, and I hope we will get an objective analysis of that.

### DEPRESSION BROCHURE

I also want to compliment your Department for another initiative. The distinguished chairman has complimented you on the AIDS mailout. I want to compliment you on the document that has been produced by the National Institute of Mental Health on depression.

I am not sure you are aware of DART—depression awareness, recognition, and treatment—but NIMH has put together a brochure on depression, that it feels all doctors and the public at large ought to heed, NIMH thinks we know enough about depression now to advise people generally of what attitudes and symptoms to look for and how we can proceed to diagnose and treat someone suffering from depression.

I think it is an excellent document, and I understand it is going national on May 3.

I want to compliment you as the titular head of the Institute, and I hope you will be involved personally in seeing that that is promoted across this country.

Secretary BOWEN. Thank you, and I will relay your compliments to the individuals who produced it.

### SCHIZOPHRENIA RESEARCH

Senator DOMENICI. Now I want to move to one last issue—schizophrenia. I am not sure that you are aware of the national program that has been developed for research in schizophrenia at the National Institute of Mental Health. But your professionals there, along with national interest groups, have developed a multiyear program for research directed at the diagnosis and cure of this terrible disease called schizophrenia.

I think you are aware that we have put that illness under the table for too long. We have got to get it out front and center, where the American people understand it is an illness. It is one of the most serious illnesses in terms of costs, in terms of patients, in terms of damage to families and friends. It is right at the top, and it is among the worst illnesses of all.

I think this 5-year research program ought to be funded so we can get on with keeping the great scientists in the field and keep the momentum in diagnosis and treatment going. We do not have enough money in your fiscal year 1989 budget to undertake the national plan for research on schizophrenia.

I hope you will take a look at it and, where you can, support funding for the national research program on schizophrenia. I need not share with you the facts. I think you know them.

But clearly, it is a far worse disease than many that we are spending 5, 10, or 20 times as much on in the National Institute of Mental Health and in your Department. I urge you to focus some attention on it.

Thank you very much, Mr. Chairman.

Secretary BOWEN. May I simply reassure you that I am, I think, on top of it. I know that the National Institute of Mental Health has made the research on schizophrenia their No. 1 priority.

Senator DOMENICI. That is right.

Secretary BOWEN. They are doing brain imaging research and have some good results on their studies. They are doing metabolic studies, genetic studies, epidemiological research, and a lot of pharmacological research.

Schizophrenic patients occupy 31 percent of all of the mental health hospital beds; 76,000 of them are there every day.

Therefore, we have $39.5 million requested for 1989, an increase of about $3 million. The treatment costs are about $7 billion annually, so if we could even reduce it by 10 percent you are saving almost $1 billion. We are working on it.

Senator DOMENICI. You are singing our tune. You have been very well advised there. That is what I was going to say, but I wanted to save time. I am glad you said it, for it is better that you say it than I.

Thank you, Mr. Chairman.

## CANCER TREATMENTS

Senator CHILES. Mr. Secretary, the question from the distinguished Senator from New Mexico about your using your persuasive ability in these areas prompts me to bring up another issue in that regard. We are spending about $1.5 billion in taxpayers' dollars for cancer research at the National Institutes of Health.

There are all kinds of wonderful, wonderful treatment modalities and other things that are coming from that research. And that is what we are spending this year. If you added up all that we spent in past years, I do not know what the number would be.

But we just see this startling figure that less than one-third of the physicians in this country are using the most up-to-date methods on treatment of cancer. That is something that is—well, it really should be intolerable, because that means that we are losing a tremendous number of lives that do not have to be lost, and we are causing tremendous savings.

And it also means that we are maybe wasting a lot of our money if we are going to develop these better treatments and in some instances cures and then find that they are not used.

I understand that we are spending only about $60 million for getting this information out. What are other ways, and how can again you use your ability as the Secretary of Health and Human Services to try to get this information out?

Secretary BOWEN. The changes in cancer therapy have come fast in the last few years, so it is understandable that those who have been in practice for a considerable period of time would not be totally up to date. That is still no excuse for not having continuing education.

Senator CHILES. Somebody who has cancer does not have very long. Changes come fast for them, too.

Secretary BOWEN. Yes; we need to get the research results to the clinical setting as fast as we possibly can. Then we need to get the physicians and the physician associations to insist on continuing medical education programs to bring the most recent treatment modalities to them.

So I think that we can exert some effort to do that with the AMA, AHA, and the various specialty groups.

Senator CHILES. I certainly hope you will exert some effort, and I hope the leadership in those groups will exert efforts, too, because it certainly is incumbent upon them to do so.

### QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

Mr. Secretary, we thank you for your appearance, and we will submit some other questions for the record.

And due to the scheduling changes in the time this morning, Senator Weicker, our ranking minority member, was unable to be here. He does have a statement and questions for the record. And Senator Hatfield also has some questions that he would like to submit to you for the record.

[The following questions were not asked at the hearing but were submitted to be answered for the record:]

## QUESTIONS SUBMITTED BY THE SUBCOMMITTEE

### REPEATED STAFF CUTS

Question. Your budget again proposes a full-time equivalent (FTE) reduction of 25 staff positions in FY 1989. Now, I support the President's program to reduce the size of the Federal Government, wherever possible, but you and your predecessors at the Office for Civil Rights (OCR) have cut staffing every single year since the Education Department was established in 1980. By my accounting, your office has been cut by about 300 FTEs -- almost in half -since 1980. Where are you headed with these policies?

Answer. The congressional budgets indicate that authorized compensable workyears decreased by 257 FTE between FY 1980 and FY 1989. However, of the decrease over 80 FTE represented permanent positions which were formally assigned to OCR at the time of the departmental reorganization but which were never filled due to budget amendments and hiring freezes.

In addition, it should be borne in mind that the FTE reductions in the early 1980's coincided with a sharp drop in the number of discrimination complaints received. Hence, OCR was able to absorb the FTE reductions while continuing to field a comprehensive compliance program.

Based on the workload estimated in the justification, the FY 1989 budget request would provide sufficient resources to effectively enforce the nondiscrimination statutes. At the same time, OCR will closely monitor the complaint workload and regularly reassess the adequacy of the staffing level. If shortfalls or other problems materialize, they will be brought to the attention of Department officials.

Question. Aren't you losing your effectiveness to enforce the civil rights laws of the nation?

Answer. OCR has taken numerous steps to increase productivity and minimize the impact of FTE reductions. We have instituted a case tracking system to monitor and help expedite case resolution. Investigative procedures are being improved and simplified where possible. Through a new and more comprehensive annual planning process, we have established concrete goals and benchmarks in processing discrimination complaints. More staff training is being provided to upgrade investigative and analytical skills. In addition, OCR plans to make greater use of ADP equipment and systems in the future to conserve staff time. These and other measures are designed to maintain work output and enhance the efficiency and effectiveness of the compliance program.

### STAFF CUTS -- INABILITY TO ENFORCE ANTI-DISCRIMINATION

Question. Two weeks ago the Federal Times reported that you were not completing quality investigations due to repeated staff cuts. I understand your full-time equivalent (FTE) ceiling has dropped by 200 since 1981. Aren't you going too far with these cuts?

Answer. OCR is taking several measures to minimize the effects of the FTE loss. These include instituting a case tracking system to monitor and help expedite case resolution, improved investigative techniques, training to upgrade investigative and analytical skills, and greater use of ADP equipment and systems. Assuming that the number of complaint receipts does not rise substantially above the projections included in the FY 1989 budget justification, the resources are sufficient to maintain work output and conduct quality investigations and reviews.

Question. Aren't you endangering the very people whose rights you're supposed to protect?

Answer. I do not believe the budget request jeopardizes the rights of minorities, of handicapped individuals, and of other persons protected against discrimination under the statutes and regulations OCR enforces. If the need for additional resources arises because of persistent increases or other changes in the workload, it will be brought to the attention of Department officials.

## PATIENT "DUMPING" AT HILL-BURTON FACILITIES

Question. Page 122 of the justification indicates that you will focus on "Hill-Burton community service provisions that prohibit improper patient transfers or 'dumping'." I am concerned about this problem and do not want to see anyone in need of emergency medical care turned away by a hospital. Please tell the Committee how many patient dumping cases you had last year. How many this year so far?

Answer. In Fiscal Year 1987 the Office for Civil Rights received 13 complaints of discrimination based on patient dumping. In Fiscal Year 1988 as of March 15, 1988 we have received seven complaints of patient dumping. In addition, since October 1, 1987, to date we have received 138 referrals of allegations that involve patient dumping. These referrals were received from the Office of the Inspector General and HCFA. Each referral is being evaluated to determine if a violation of any of OCR's authorities exist.

Question. What do you do when you find out that a hospital has been "dumping" patients?

Answer. Once an investigation reveals that patient dumping has occurred, OCR follows standard procedures that include issuing a Letter of Findings to the recipient describing violation(s). The letter also outlines acceptable remedies and offers technical assistance to the recipient so that the matter may be voluntarily resolved. The remedies sought meet the requirements of the regulations and comply with internally set standards.

All complaints received directly by OCR alleging patient dumping issues are made known to the OIG and HCFA. A copy of the incoming complaint is forwarded to those offices. There will be instances when the recipient has violated COBRA requirements and the OCR investigation will not extend to such a violation. For example, if the review by OCR is under the Hill-Burton regulation and Section 504, and the investigation reveals that the complainant is not a resident of the service area, then the complainant will not be covered under the Hill-Burton regulation, thus a denial of service based on issues other than handicap will not be covered in the investigation.

Question. Have you ever punished any hospitals for violating the anti-dumping provisions of the Hill-Burton program?

Answer. When a hospital is found to be in violation of the anti-dumping provisions, our approach is to develop a corrective action plan. In all of our investigated patient dumping cases where we have found problems, we have negotiated agreements with recipients that have resulted in obtaining some form of change in the recipients policies or practices that result in problems of patient dumping. For example, we have effected changes that have abolished practices of allowing only a certain quota of medicaid patients into emergency rooms for treatment; and we have negotiated agreements that will allow patients into emergency rooms for emergency treatment regardless of the patients' past history of disruptive behavior or payment record.

Question. What enforcement tools do you have to punish hospitals that deny emergency medical care to persons in need of it?

Answer. The enforcement tools available to the Office for Civil Rights involve the process of either administrative hearings within the Department or referrals to the Department of Justice requesting an action against the facility. For a Hill-Burton violation, OCR will through the Department of Justice, seek a court order requiring the Hill-Burton recipient to meet its community service obligation. The ultimate penalty for violation of authorities other than Hill-Burton is the termination of Federal financial assistance from this Department. These processes do not include monetary or criminal penalties.

Question. Can anyone in the Department punish hospitals that deny treatment? What are those penalties?

Answer. In addition to OCR's authorities, under COBRA, the HCFA and the OIG can terminate a hospital's participation in the Medicare program as well as impose civil monetary penalties of up to $50,000 on the hospital or a physician or on both.

## COMPLAINT WORKLOAD

Question. The budget justification indicates that you received 1,148 complaints last year. I recognize that some of those complaints may still be under review. Approximately how many of the 1,148 complaints were valid?

Answer. OCR is required to investigate all complaints of discrimination for which we have jurisdiction on the basis of program and HHS resources; 130 of OCR's investigations of complaints received in FY 1987 that have been completed as of May 11, have resulted in changes in policies, practices or procedures.

Question. Of those that were valid, what did you do about the discrimination that you found?

Answer. In 38 of the 130 cases, the facility or service provider corrected a potentially discriminatory policy or practice prior to a formal finding by the Office for Civil Rights. In 53 cases, OCR negotiated a corrective action plan with the facility or provider. OCR will monitor implementation of these plans. In six cases, changes were made as a result of negotiations between the complainant and the recipient prior to an OCR investigation. Finally, in 33 cases, the complainant withdrew the complaint after achieving a change that was satisfactory to him or her.

Question. Did you levy any penalties against those institutions found to have violated the civil rights of HHS beneficiaries?

Answer. OCR makes every effort to encourage and assist recipients to resolve complaints voluntarily. OCR was able to achieve change in the cases that I previously mentioned without having to initiate administrative or enforcement proceedings.

## REFERRALS TO JUSTICE DEPARTMENT AND ENFORCEMENT

Question. Page 128 of the justification states that the legal staff "refers cases to the Department of Justice for enforcement." How many cases were referred last year? For the last five years?

Answer. During the last year, no cases were referred to the Department of Justice. There were two cases referred during the last five years.

Question. How many cases has the Justice Department litigated during the last five years? How many have they won?

Answer. In the last five years the Department of Justice has litigated three cases, winning two of them. One of these cases was referred in 1981.

Question. Do you have adequate enforcement tools to ensure civil rights protections, short of referring cases to Justice? Could you describe them?

Answer. Referral of civil rights actions to the Department of Justice (DOJ) for judicial enforcement is only one enforcement option available to OCR. Pursuant to regulations implementing civil rights statutes enforced by OCR, another alternative is administrative enforcement. As with referrals to DOJ, this enforcement option is available to OCR when a recipient has been found in violation and fails to comply voluntarily. An administrative enforcement action affords a recipient found in noncompliance an opportunity for an administrative hearing before an administrative law judge. A final decision rendered pursuant to this process, if adverse to the recipient, will result in the termination of Federal financial assistance to the recipient unless it then comes into compliance. Prior to commencement of either judicial or administrative enforcement actions, compliance is often obtained through voluntary compliance agreements. These agreements commit the recipients to take steps to remedy those actions found to be in noncompliance.

## PROCESS-ORIENTED WORK

Question. Most of the tables in the justification suggest work that is process-oriented, such as "compliance reviews", "pre-grant reviews" or "monitoring" workloads. Can you explain what are the actual outcomes of your work?

Answer. The tables in the justification describe current and anticipated OCR workload by indicating the number of reviews, discrimination complaints, and monitoring actions worked on by the staff.

Civil rights compliance problems or violations may be identified during the course of complaint investigations or reviews. In such cases, program recipients must take corrective action to eliminate or prevent the discrimination. For example, of the 360 complaint cases completed in FY 1987 which required a full investigation, corrective action or change was taken in 132 cases. Of the 171 comprehensive compliance reviews completed in FY 1987, 118 of the reviews, or 69 percent, resulted in corrective action. Of 258 project reviews completed, 106 of the reviews, or 41 percent, resulted in corrective action in FY 1987.

Question. Do you produce specific products such as administrative sanctions or judicial convictions against those found to have violated civil rights laws?

Answer. In the overwhelming number of cases where OCR finds compliance problems or violations, program recipients agree to take remedial action on a voluntary basis. The nondiscrimination statutes provide for enforcement action if a program recipient does not voluntarily comply with civil rights requirements. In such cases, OCR may offer the recipient an administrative hearing or refer the case to the Justice Department for court action. The administrative sanction provided by law is termination of funds.

## FEDERAL EMPLOYEES RETIREMENT SYSTEM (FERS)

Question. Last year the Committee approved nearly $400,000 for the Federal Employees Retirement System (FERS) based on an expectation that about one out of five employees, or 20 percent, would enroll in FERS. I understand that less than 5 percent of your employees enrolled in FERS as of last December. Does that free up any of the monies the Committee made available for FERS?

Answer. More recent figures show that over 7.5 percent of OCR's employees are enrolled in FERS. FERS costs will continue to rise with thrift plan enrollments and replacement of personnel separations. Also, the second open season may result in additional FERS related costs. Additionally, there is currently a second open season whereby CSRS employees can transfer to FERS. This could further add to OCR's costs for FERS in FY 1988.

Question. If so, what are your plans for the extra funds? Will you be seeking to reprogram those funds?

Answer. There are no "extra" funds. OCR has had to meet additional costs not anticipated or budgeted for in the FY 1988 congressional budget. For example, OCR has had to absorb the cost of the January 1988 pay raise, estimated at $229,000. Space rental charges increased by $86,000 over the amount projected in the FY 1988 budget.

## AVERAGE GRADE FOR OCR EMPLOYEES

Question. Page 115 of the justification says you will have lower grade hiring, yet your average grade (page 117) seems to be going up. What is your policy on this?

Answer. Because of annual FTE reductions, constrained hiring, and the comparatively low grades of persons leaving, OCR has experienced persistent increases in the average grade of the staff. Our policy is to attempt to moderate this trend by hiring replacements (when possible, given employment ceilings) at the lowest grade possible.

Question. Do you really need an average grade of 11.33?

Answer. OCR does not have an average grade standard. Persons who have left OCR generally have been lower-graded than those remaining, thus the average grade increases. We have partially offset this trend by hiring replacements at lower grades than that of departing staff.

## OFFICE SPACE RENTAL COSTS

Question. A large increase in your budget request is for office rent -- $247,000 rise -- 15 percent more. How can these costs go up so much when you had a staff reduction this year and are proposing another in FY 1989?

Answer. Over the past several years, regional office relocations and space reductions in headquarters have reduced OCR's total office space. However, these moves have not offset sharp rate increases in rental payments. During the last two fiscal years (FY 1986-88), rental payments to GSA increased 36 percent. The FY 1989 budget assumes a rate increase of 15 percent.

Question. The President has set a standard of 135 square feet per employee. How are you doing in meeting this standard?

Answer. During the past three years OCR has been consolidating space both in the regional offices and in headquarters. In addition, space reductions are planned for the OCR Regional Offices in Atlanta, Chicago, and Seattle.

Question. What is your square footage of office space per employee?

Answer. At the present time OCR is utilizing an average of 160 square feet of office space per work station. OCR anticipates that the average will be further reduced in the regions and headquarters and that the Administration's goal will be met.

## ANALYSIS OF PERSONS WITHOUT HEALTH INSURANCE

Question. I note on page 142 of the justification that this year you will complete an analysis of health insurance for uninsured persons.

Massachusetts just enacted its own law establishing a program for health coverage for the uninsured -- how does your research relate to a development like that?

Answer. Massachusetts' program imposes mandatory obligations on employers to cover the costs of health care for workers. Our research should provide a basis for comparing the impact of the Massachusetts type of legislation (or similar mandates in other state or Federal law) with more voluntaristic and pluralistic remedies that avoid placing undue burdens on employers. These "gap-filling" approaches include multiple employer trust arrangements.

Question. Do you work with the States in developing these types of projects and subsequent legislation?

Answer. We monitor initiatives being tested by States, for example, the group of demonstrations sponsored by the Robert Wood Johnson Foundation. The research is of a generic nature. While intended to provide information that could, among other things, be useful to States in framing subsequent legislation, our efforts do not involve direct coordination with States' projects or legislation. It is, however, made available to them.

## LONG-TERM CARE CHANNELING DEMONSTRATIONS

Question. You note on page 144 of the justification that this year you evaluated the Long-Term Care Channeling Demonstrations. This five year project studied the cost-effectiveness of community based long-term care.

How much was spent over the five year life of this project?

Answer. The National Long Term Care Channeling Demonstration was an HHS intradepartmental policy research initiative involving 10 states, a technical assistance contractor and a national evaluator. It was funded by the Health Care Financing Administration

(HCFA), the Administration on Aging (AoA), and the Assistant Secretary for Planning and Evaluation (ASPE). The total cost of the demonstration was approximately $40 million. Expenditures under the Channeling Demonstration are as follows:

- o The ten demonstration projects incurred costs of $23 million as they prepared for and subsequently provided case management and long-term care services to 7,200 clients. Altogether, over 51,000 ongoing case months of service were provided.

- o The five basic case management projects spent $4.6 million and the five financial control projects spent $5.1 million to perform the core channeling and administration functions (ie; case finding, screening, initial needs assessment, initial core planning, and ongoing case management). (Included in the $23 million)

- o In addition, the five financial control projects spent $12 million to purchase direct services, while the five basic case management projects spent $800,000 for gap filling services. The projects spent most of this money for homemaker/personal care, skilled nursing, and home health aide services. (Included in the $23 million)

- o In addition to the direct costs of operating Channeling agencies, the states incurred $2.8 million in administrative costs, the technical assistance contractor spent $1.6 million and the cost to carry out the evaluation was $13 million. Over 5000 people participated in the research sample which involved interviews at baseline 6 months, 12 months and 18 months.

Question. What are the results of the evaluation?

Answer. HHS established the Channeling Demonstration Program as a rigorous test of comprehensive case management of community care as a way to contain the rapidly increasing costs of long-term care for the impaired elderly while providing adequate care to those in need. Two channeling models were tested. Both models offered individuals who were at risk of institutionalization a systematic assessment of their needs and ongoing case management to arrange and monitor the provision of services. The models differed with respect to how community services were provided to clients. One model, the basic case management model, managed services that were available to clients in the community and added a modest amount of funding for purchasing services that were unavailable through other sources.

The second model, the financial control model, expanded the range and availability of publicly financed services but, at the same time, instituted cost control features that placed a cap on average and per-client expenditures. The goal of the evaluation was to identify the impact of the two Channeling models on the need of formal health and long term care services, on public and private health and long term care expenditures, on mortality functioning and client well being and on the amount of informal care provided by family and friends. To identify impacts, the evaluation relied on an experimental design with random assignment of sample members to a treatment or control group.

Findings:

- Both Channeling models increased formal community service use. The income was substantial under the financial control model.
- The increased service use did not lead to reductions in the provision of care by families although the financial control model led to small reductions the care provided by friends and neighbors.
- Despite success in targeting an extremely frail population, channeling did not identify a population at high risk of nursing home placement, and did not substantially reduce nursing home use.
- The Channeling population was frequently hospitalized and made heavy use of physicians and other medical services. Channeling did not affect these types of service use.
- The cost of expanding case management and community services were not offset by reductions in nursing home or other costs.
- Channeling reduced unmet needs, increased clients' confidence in receipt of care, and increased their satisfaction with life.
- Channeling increased informal caregivers' satisfaction with service arrangements and satisfaction with life.
- Channeling did not affect measures of client functioning, with the possible exception of physical functioning under the financial control model.
- The Channeling population was at high risk of dying. Channeling did not affect mortality.

Overall Conclusion From the Channeling Findings:

The evidence from Channeling suggest that expanding case management and community care cannot be justified on the bases of cost savings. Such expansion would have to be based on the expected benefits -- increased levels of service, fewer unmet needs and greater satisfaction among clients and their caregivers.

We have attached a summary of the Final Evaluation Report for your information.

Question. Where do you go from here?

Answer. Ten years of reach and demonstration conducted by the Department of Health and Human Services has shown that expanding publicly financed community care does not reduce aggregate costs and is likely to increase them. Nor do these services have any effect on extending life or improving physical functioning. Nevertheless, case management and community-based services are an extremely important part of the long-term care continuum. While they do not substitute for nursing home care, they do have positive effects on the quality of life of frail older people and through families .

The principal questions before us now are: how much as a society do we wish to invest in publicly financed community care; who should receive it; and how should it be organized. The first question is largely a political issue. Our research and demonstration experience provided suggests that the appropriate target groups for home care should be people with multiple impairments who lack family supports. We are continuing to examine through additional research, the most efficient ways to organize and deliver community care. We have appended a copy of a recent study of community care organization at the State level which you may find of interest.

## WORKING WITH THE INSPECTOR GENERAL

Question. Now, both you and the Office of the Inspector General do evaluative studies. I see from the justification that some of those studies are on the same program topics.

Do you work closely together with the Inspector General on studies?

Answer. Yes, we do work closely with the Inspector General.

Question. How do you ensure that one office does not duplicate efforts of the other?

Answer. We and the Office of the Inspector General (OIG) work closely in planning, conducting and utilizing results of evaluative studies. For example, we exchange and review draft plans with the OIG. This both avoids duplication and ensures a focus on issues important to each office. We may both conduct a study of the same important issue, but will coordinate the projects to ensure the results are cumulative. In these cases, we review and integrate specifically what will be examined and how it will be done. We also exchange project results in draft and in final, particularly those with significant policy or budget implications. Finally, we operate a Policy Information Center that maintains computerized summaries of the findings of all evaluative studies concerning HHS activities; those we fund, those conducted by the OIG, and those conducted by other offices, including the GAO. Thus, all study results on a particular program or subject can be reviewed.

Question. How about developing legislative proposals? Do you work together in the development of legislative proposals, known as the "A-19" process?

Answer. We work very closely together in developing proposals. For example, we chair legislative teams that review all HHS proposed legislation, including those developed by the OIG. These teams include OIG staff representatives, so the OIG may provide advice on all HHS proposals. We also have informal staff discussions with the OIG on proposed legislation, particularly cost saving proposals.

## GENERAL COUNSEL STAFFING INCREASE

Question. Page 55 of the justification summarizes your request for 14 additional staff positions in the General Counsel's office, based on an expectation that the Department will be sued more in Medicare Part B cases. Why does the Department expect more law suits next year?

Answer. The additional staff positions are requested because of anticipated increases in both sanction activity and Part B litigation.

Increased sanction activity is anticipated because Congress has greatly increased the types of offenses which are subject to civil money penalties and other sanctions. In particular, the Omnibus Budget Reconciliation Act (OBRA) of 1987 and the Medicare and Medicaid Patient and Protection Act of 1987 significantly expanded the Department's authority to impose sanctions against health care providers and practitioners who engage in various types of misconduct. This new legislation, in conjunction with pre-existing law, means that there are now approximately 40 types of activities which can serve as the basis for imposition of a civil money penalty. There are also some 50 types of activities which can serve as the basis for an exclusion from participation in the Medicare and, in many cases, the Medicaid programs. Twenty of those types of activity can serve as the basis for both types of sanction. It is anticipated that the Office of Inspector General, which identifies cases for sanction, will aggressively institute cases under these new authorities. Such cases can be particularly draining on legal resources, since they are trial-type proceedings which can be quite lengthy.

Additional law suits involving Part B are expected because Congress recently amended the Medicare law to make such cases subject to judicial review for the first time. Prior to 1987, the Medicare statute did not provide for administrative or judicial review of Part B payment or coverage determinations beyond a hearing held by the Medicare carrier. However, in section 9341 of the OBRA of 1986, Congress created new appeal rights for Part B cases, effective for items and services rendered on or after January 1, 1987. Under this new authority, a hearing is available before an administrative law judge when the amount in controversy is $500 or more, and judicial review is available when $1000 or more is at issue.

Although the number of Part B determinations which are contested is a small percentage of the total number of determinations, it is still a significant number. For example, in FY 1987 there were 48,366 carrier hearings (the first step in the administrative review process), and in the first two quarters of FY 1988 there have been 30,956 -- none of which could have been appealed to the courts before the new legislation. It is anticipated that most of these cases will continue to be resolved at the administrative level, without resort to the courts. Nevertheless, the newly appealable cases are just now beginning to move through the review process and, subsequently, into the courts. Thus, the potential exists for a large number of additional court cases.

## DEBT COLLECTION

Question. Please explain for the Committee how much outstanding debt the Department expects to collect next year.

-- From what programs does most of the HHS debt come?

Answer. The Department expects to collect $10.4 billion in outstanding debt in FY 1988, and $10.9 billion in FY 1989. Of the Department's total debt, 98% is attributable to Social Security programs (35%) and Medicare programs (63%). The remaining 2% is spread across the Department's other programs.

Question. How much debt is not collected and is written off each year?

Answer. In FY 1987, $230 million in debt was written off; 99% of this was attributable to Social Security Act beneficiaries. It is projected that $287 million will be written off in FY 1988, and $252 million in FY 1989. Of these amounts, 90% in FY 1988 and 97% in FY 1989 will be attributable to Social Security Act beneficiaries.

## AUDIT OF THE WORKING CAPITAL FUND

Question. What protections do you have to ensure that the Working Capital Fund is doing what it was set up to do and is not overcharging the Public Health Service (PHS), the Social Security Administration (SSA), and the other agencies in the Department?

Answer. A Working Capital Fund Charter was approved by the Board of Governors in FY 1987. The Charter provides for representation on the Board by a senior level representative from each of the five Operating Divisions of the Department, and one representative from each of the major Staff Divisions involved in providing WCF services (i.e., the Office of the Assistant Secretary for Management and Budget (ASMB), the Office of the Assistant Secretary for Personnel Administration (ASPER), and the Office of the General Counsel (OGC)). The Office of the Inspector General is an ex-officio member of the Board. The Assistant Secretary for Management and Budget serves as Borad Chairperson. The Board has multiple responsibilities and authorities for assuring that appropriate controls on Fund operations are maintained. The Charter also provides for an annual audit of the Fund, the procedures for which are subject to the approval of the HHS Inspector General.

The Board recently apporved the concept of User Groups consisting of Operating Division customers of Fund services and the providers of those services in the Office of the Secretary. Several of these user groups are currently functioning with more groups planned for FY 1989. In addition, the Board approved a Budget Work Group consisting of OPDIV representatives to examine the budgets of the OS service providers and to make budget recommendations to the Board.

Question. Do you have plans to audit the fund?

Answer. The required annual audit of the Fund is currently underway which includes an audit of the Fund's year-end financial statement. The audit also includes a review of the charges to the Operating Divisions and a review of the pricing and allocation formulas to assure that the OPDIVs are not being overcharged for services.

## WORKING CAPITAL FUND CHARGES BY AGENCY

Question. Page 60 of the justification breaks down the Working Capital Fund (WCF) charges by Operating Division in the Department. For the record, would you provide, by type of service rendered, for fiscal years 1988 and 1989:

1. How much the WCF charges each agency in the Public Health Service?

Answer. With the exception of the Reprographics and Unique Supplies service activities which are billed on a fee-for-service basis, Working Capital Fund activities are billed to the Operating Divisions on an allocable basis. The requested data by activity for the Public Health Service for FY 1988 and FY 1989 are provided in Tables 1 and 2 on the following pages.

## TABLE 1

### PUBLIC HEALTH SERVICE
### WORKING CAPITAL FUND
### COMPARABLE ESTIMATES BY AGENCY

### FY 1988

| Function | FDA | HRSA | IHS | CDC | NIH | ADAMHA | OASH | Total |
|---|---|---|---|---|---|---|---|---|
| Payroll and Personnel..... | $ 893,000 | $ 1,567,000 | $ 844,000 | $ 481,000 | $1,521,000 | $191,000 | $ 160,000 | $ 5,657,000 |
| Payment Management System. | — | 353,000 | — | 53,000 | 2,065,000 | 219,000 | 25,000 | 2,715,000 |
| Finance and Accounting.... | — | 296,000 | — | 34,000 | 81,000 | 17,000 | 13,000 | 441,000 |
| WCF Management............ | 5,000 | 15,000 | 10,000 | 4,000 | 26,000 | 4,000 | 1,000 | 65,000 |
| Regional Finance and Administration..... | — | 1,026,000 | 378,000 | 147,000 | 1,362,000 | 93,000 | 95,000 | 3,101,000 |
| Regional Legal Services... | 16,000 | 287,000 | 287,000 | — | — | — | — | 590,000 |
| Correspondence Control... | 11,000 | 19,000 | 7,000 | 9,000 | 23,000 | 15,000 | 37,000 | 121,000 |
| Total.................. | $ 925,000 | $ 3,563,000 | $1,526,000 | $ 728,000 | $5,078,000 | $ 539,000 | $ 331,000 | $12,690,000 |

## TABLE 2

## PUBLIC HEALTH SERVICE
## WORKING CAPITAL FUND
## COMPARABLE ESTIMATES BY AGENCY

FY 1989

| Function | FDA | HRSA | IHS | CDC | NIH | ADAMHA | CASH | Total |
|---|---|---|---|---|---|---|---|---|
| Payroll and Personnel..... | $ 996,000 | $ 1,628,000 | $1,582,000 | $ 604,000 | $1,778,000 | $225,000 | $ 201,000 | $ 7,014,000 |
| Payment Management System. | — | 376,000 | — | 57,000 | 2,209,000 | 234,000 | 27,000 | 2,903,000 |
| Finance and Accounting.... | — | 392,000 | — | 45,000 | 107,000 | 24,000 | 17,000 | 585,000 |
| WCF Management............ | 8,000 | 33,000 | 19,000 | 6,000 | 42,000 | 5,000 | 4,000 | 117,000 |
| Regional Finance and Administration..... | — | 1,619,000 | 631,000 | 230,000 | 1,388,000 | 95,000 | 163,000 | 4,126,000 |
| Regional Legal Services... | 8,000 | 151,000 | 148,000 | — | — | — | — | 307,000 |
| Capital Investment........ | 7,000 | 29,000 | 17,000 | 6,000 | 36,000 | 4,000 | 3,000 | 102,000 |
| Total................. | $1,019,000 | $ 4,228,000 | $2,397,000 | $ 948,000 | $5,560,000 | $587,000 | $415,000 | $15,154,000 |

Question. Page 60 of the justification breaks down the Working Capital Fund (WCF) charges by Operating Division in the Department. For the record, would you provide, by type of service rendered, for fiscal years 1988 and 1989:

2. How much it charges the Staff Divisions in the Office of the Secretary?

Answer. With the exception of the Reprographics and Unique Supplies service activities which are billed on a fee-for-service basis, Working Capital Fund activities are billed to the Operating Divisions on an allocable basis. The requested data by activity for the Office of the Secretary for FY 1988 and FY 1989 are provided in Tables 3 and 4 on the following pages.

## TABLE 3

## OFFICE OF THE SECRETARY
## WORKING CAPITAL FUND
## COMPARABLE ESTIMATES BY STAFF DIVISION

FY 1988

| Function | Office for Civil Rights | Office of Inspector Gen. | Office of Consumer Aff. | Policy Research | Departmental Management | Total |
|---|---|---|---|---|---|---|
| Payroll and Personnel........ | $ 481,200 | $ 1,107,200 | $54,700 | $24,000 | $ 2,602,900 | $ 4,270,000 |
| Payment Management System.... | - | 39,000 | - | - | - | 39,000 |
| Finance and Accounting...... | 323,900 | 571,400 | 29,500 | 65,400 | 1,605,800 | 2,596,000 |
| WCF Management............... | 7,300 | 19,900 | 600 | 600 | 42,600 | 71,000 |
| Regional Finance and Administration...... | 244,000 | 713,000 | - | - | 1,079,000 | 2,036,000 |
| Regional Legal Services...... | - | 415,000 | - | - | 807,000 | 1,222,000 |
| Correspondence Control........ | 3,600 | 12,500 | 200 | - | 21,700 | 38,000 |
| Total.................. | $ 1,060,000 | $ 2,878,000 | $85,000 | $90,000 | $ 6,159,000 | $ 10,272,000 |

## TABLE 4

## OFFICE OF THE SECRETARY
## WORKING CAPITAL FUND
## COMPARABLE ESTIMATES BY STAFF DIVISION

## FY 1989

| Function | Office for Civil Rights | Office of Inspector Gen. | Office of Consumer Aff. | Policy Research | Departmental Management | Total |
|---|---|---|---|---|---|---|
| Payroll and Personnel........ | $ 251,300 | $ 381,100 | $ 34,000 | $ 6,100 | $ 1,865,500 | $ 2,538,000 |
| Payment Management System.... | - | 42,000 | - | - | - | 42,000 |
| Finance and Accounting...... | 83,600 | 80,000 | 46,600 | 12,500 | 2,384,300 | 2,607,000 |
| WCF Management............... | 4,800 | 19,400 | 800 | 200 | 67,800 | 93,000 |
| Regional Finance and Administration...... | 169,000 | 201,900 | - | - | 1,488,100 | 1,859,000 |
| Regional Legal Services...... | - | 1,315,500 | - | - | 1,315,500 | 2,631,000 |
| Capital Investment........ | 4,300 | 17,100 | 600 | 200 | 59,800 | 82,000 |
| Total.................. | $ 513,000 | $ 2,057,000 | $ 82,000 | $ 19,000 | $ 7,181,000 | $ 9,852,000 |

## OFFICE SPACE COSTS

Question. Mr. McCann, yours is about the only budget request I've seen in a long while that reduces rental payments to GSA. You must be doing something right. In fact, your budget request proposes to decrease rental payments by $2.2 million, or 19 percent, from last year's $11.4 million appropriation.

— Can you explain for the Committee how you will be able to reduce the rent budget in 1989?

Answer. The lower request is the result of an interaction between rental rate increases, office space reductions, and a reallocation of space between the General Departmental Management (GDM) and Working Capital Fund (WCF) accounts to more accurately reflect current usage.

- o Average rental rates for office space are projected by GSA to increase by 14% between FY 1988 and FY 1989.
- o Our Work Space Management Plan projects decreases of 28,000 sq. ft. in office space (a 6% reduction) and 9,000 sq. ft. in non-office space (a 3% reduction) between FY 1988 and FY 1989. During this same period, we project the need for 131 additional workstations (a 5% increase), due to the increased use of contractors and the addition of computer workstations.
- o Extensive use of systems furniture in the Department's headquarters buildings is facilitating more efficient use of space, as well as enhancing the work environment. Installation of as many as 1,500 systems units during FYs 1988 and 1989 will have a payback period of approximately 36 months, through savings achieved via space reduction.
- o Adjusted office space utilization (end of year):
  FY 1988 = 147 sq. ft./workstation
  FY 1989 = 128 sq. ft./workstation
- o The WCF is incurring an increased share of rental costs in FY 1989. When the FY 1988 rental budget was formulated, uncertainty existed as to how many FTEs and functions would ultimately be approved for the WCF; consequently, rental estimates for the WCF were conservative. The current allocation, as shown below, is based upon a proportional share of actual FTEs and space occupied (dollars are in thousands).

| | | GDM | WCF |
|---|---|---|---|
| FY 1988 | Rent | $11,424 | $ 6,135 |
| | FTEs | 955 | 1,193 |
| FY 1989 | Rent | $ 9,204 | $11,791 |
| | FTEs | 958 | 1,181 |

## COOPERATIVE ADMINISTRATIVE SUPPORT UNITS

Question. The justification talks about managing cooperative administrative support units (CASUs) in the Department's Kansas City and New York Regional offices.

As I understand it, these units provide centralized administrative services, such as mail delivery, printing, and warehousing, to all Federal offices in the regional building in those cities. How is the project working so far?

Answer. Memoranda of Understanding (MOUs) have been signed with multiple Federal agency tenants of the Kansas City Federal Building at 601 East 12th Street to participate in all or some of the services offered by the CASU. In addition, other Federal agencies outside of the Federal Building at 601 East 12th Street, are participating in the CASU's Employee Assistance contract with a total of 39 participating agencies with 17,533 employees in more than 30 states covered by this contract.

CASU services chartered to date in Kansas City include: Labor/Moving, Personal Property Services, Employee Assistance, General Maintenance Agreements, Conference and Training Room Management, Imprest Fund and Procurement. Additional services authorized for study are: child care and physical fitness. At a later date, the CASU anticipates implementing functions such as common-needs training, maintenance agreements for ADP equipment, records disposition, shredding, space management, telecommunications, telecopying and warehousing.

The New York CASU, which was chartered in November 1987, is in the preliminary stages of establishing its program.

Question. Will the Government realize any budget savings from it?

Answer. Combined savings from the CASUs when fully operational in both regions are projected to be over $1 million in tangible and intangible savings. As the CASUs expand their service offerings and participation by agencies increases, the participating agencies are also expected to realize significant cost savings.

## AFDC EMPLOYMENT PROGRAM

Question. In its budget submission, the Administration plans to eliminate the work Incentive (WIN) program and support the work and training program contained in the AFDC Employment and Training Act of 1987, S. 1655 and H.R.3200, which would allow States to provide services allowed under WIN, WIN Demonstrations, and other work options. (The House, however, rejected H.R. 3200, passing instead the Family Welfare Reform Act of 1987, H.R. 1720). The Senate is expected to consider the Family Security Act of 1987, S. 1511.) S. 1655 would require States to achieve specific levels of participation, increasing over time until a substantial portion of the caseload is in the program. The program's employment and training services would be funded as an authorization rather than as an entitlement as in H.R. 1720 and S. 1511. The Administration projects about the same Federal funding level in 1989 that the States received for these types of programs in 1985. GAO's work has shown that in 1985 States were spreading their AFDC work program resources thinly and were on average able to offer only minimal services to less than a quarter of their caseloads. Although the Administration projects increased funding for years beyond 1989, such amounts would not be significantly higher than pre-1981 WIN levels (certainly not when adjusted for inflation). If the program is funded at the levels the Administration projects, to what extent will the States be able to provide the intensive training and education services many AFDC recipients need and still meet the participation requirements for their caseloads?

Answer. For the first several years, we are projecting that $500 million in funding will be more than adequate for States to meet the program's participation requirements. This is almost double the 1985 budget authority for WIN and IV-A work activities, and would allow spending almost triple the 1985 Federal and State funding. In addition, the participation requirements in this legislation are modest and phased in over a long period of time. Also, research has shown that a broad range of recipients can benefit from services like employment search and work experience that are not particularly intensive or expensive. Finally, we assume that AFDC recipients will continue to receive a substantial portion of their education and training services from alternative sources, including the Job Training Partnership Act program.

Question. If the current austere budget environment results in reduced program funding, to what extent will States have to compromise program quality to meet stringent participation requirements? If the intensity of services is reduced, will this not result in reduced program savings in the long run, because the most disadvantaged recipients will not get the services they need to help them achieve self-sufficiency?

Answer. As we have indicated previously, the funding in H.R. 3200 S. 1565 will allow substantial increases in employment and training programs, and the participation requirements in the AFDC Employment and Training Reorganization Act are not very stringent.

Also, research has shown that non-intensive services can be effective in reducing dependency among a broad range of recipients.

## CHILD SUPPORT ENFORCEMENT

Question. In recent testimony, GAO questioned the reliability and useful of data the Office of Child Support Enforcement (OCSE) obtains from States on caseloads and collection of child support payments and in turn reports to Congress. OCSE also has found these data to be incomplete and inconsistent. Without good data, the Congress is unable to assess program performance. What step is OCSE taking to correct the deficiencies and ensure reliable and consistent data are available to the Congress?

Answer. OCSE has audited the reliability of State statistical reporting and has required corrective action. OCSE regularly performs variance analysis of State-reported data and requires explanations by States of reported data which appears questionable. Automation efforts underway in several States will enhance States'capability to report accurately and timely.

Question. GAO also testified that although the Social Security Act requires OCSE to establish standards to assure that State child support programs are effective, there are no federal standards to assess how effectively agencies locate parents, determine paternity, or obtain and enforce support orders. HHS has stated that OCSE plans to develop performance standards for paternity establishment. What is the status of plans to develop paternity establishment standards and does OCSE intend to develop standards for other aspects of the child support enforcement program?

Answer. We have already strengthened the paternity establishment standard for purposes of the audit of State child support enforcement programs. On September 14, 1987, we notified States that, beginning with audits conducted for FY 1988, the standard to be applied to State and local efforts to establish paternity would be based on the actual establishment of paternity and support orders or the initiation of legal action to establish paternity and obtain support orders in at least 75 percent of the cases reviewed requiring this service where the absent parent had been located. Additional details regarding this standard were issued to the States by program instruction on May 5, 1988.

With respect to standards for the program in general, proposed regulations are currently under review within the Department which would impose processing standards for all aspects of State child support enforcement programs -- locating the absent parent, establishing paternity and support obligations and enforcing those obligations. The proposed regulation would impose new, as well as clarify, or update existing or vague, time frames and requirements. Those proposed regulations are scheduled to be published in August.

Question. GAO also testified on the need for better case management (tracking and monitoring), especially of interstate cases. OCSE's recent regulations require States to establish central registries or inventories of such cases, which OCSE believes will improve States' ability to trace cases. How will establishing central state registries improve tracking and monitoring? Also, who now has primary responsibility for tracking interstate cases -- initiating states, responding states, or both, and what is the federal role?

Answer. Central registries will alleviate a major problem in interstate case processing -- the fact that, once an initiating State sends an interstate case to responding State, the initiating State is unable to determine where the case was sent for action within the responding State and if any action is being taken. Prior to the requirement that States establish central registries for interstate cases, in many States, no single individual or office had oversight responsibility for interstate case processing. Central registries would have that oversight responsibility. They would receive all incoming interstate child support enforcement cases, conduct an initial review of the case to determine the adequacy of the documentation provided, forward the case for necessary action, acknowledge receipt of the case, inform the initiating State where the case was sent, and respond to inquiries on the status of cases upon request -- all within 10 days of receipt of the case.

Both initiating and responding States are responsible for tracking interstate cases. The initiating State agency should work closely with the responding State jurisdiction actually working the interstate case. Both agencies are responsible for tracking the progress of the case. If problems arise, for example, no action is being taken on a case, or a case is lost in the process, the initiating State central registry must, upon request, locate the case and ensure the case is being worked. The Federal government's role is to ensure, through audits of State programs, that States are meeting the requirements for processing interstate cases which are contained in Federal regulations.

Question. GAO also testified with respect to interstate child support enforcement that less than half the States have automated their case tracking systems for all child support enforcement functions--despite (1) indications that automation substantially improves case processing, and (2) the availability of federal funding incentives for automation. What steps is OCSE taking to further encourage States to automate their processes?

Answer. Since 1982, OCSE has undertaken a number of activities to promote automation. OCSE has held national systems conferences for 3 years to provide a forum for comprehensive systems. In addition, guidelines and technical assistance documents were published.

Following enactment of the Child Support Enforcement Amendments of 1984 which resulted in greater uniformity among State child support programs, we began to strongly urge transfer of tested and proven systems from one State to another. As a result of these concerted efforts, 37 States already have statewide comprehensive projects underway.

Question. Do the fifty-four jurisdictions which operate AFDC programs now operate systems that meet the IEVS requirement?

Answer. As of January 1, 1988 all but five of the 54 jurisdictions have submitted State plan amendments on IEVS. Of the 49 amendments approved, 42 have been permitted to delay implementation of one or more of the matches.

California with about 60% of its caseload under IEVS review is fairly typical. Los Angeles is coming "on-line" during May, 1988 and the State will have about 80% of the caseload covered. California officials expect to be fully operational on September 28, 1988.

Question. How effective are the systems in verifying income eligibility?

Answer. FSA does not have any comprehensive information immediately available to evaluate effectiveness at this time.

The Notice of Proposed Rule Making which promulgated IEVS, issued on March 14, 1986, required States to maintain records for tracking the status of match results and for reporting data on the actions taken and the savings realized for each match. This proposed requirement brought forth thirty letters of comment, many complaining that such a tracking system would be costly to develop and difficult to maintain and would not produce reliable data on savings and cost avoidance.

The final rule for IEVS issued on February 28, 1987 responded to these comments by curtailing these reporting requirements. Current regulations at 45 CFR 205.60 require only that the State maintain records with respect to individual applications denied, recipients whose benefits have been terminated, recipients whose benefits have been modified, and the dollar value of these denials, terminations, and modifications. However, the requirement to report this information regularly was dropped in favor of making it available upon request. No requests have been made or studies conducted as of this time.

We made telephone contact with several of the larger States to determine availability of data on the effectiveness of IEVS. Ohio estimated that IEVS caused 510 terminations and 26 reductions per year for an estimated savings of $1.4 million.

Michigan estimated that matching caused 1358 terminations and 1183 reductions per year. In addition, about 18 applications are denied per year. The latter figure reflects the provision that authorization cannot be delayed pending receipt of IEVS information.

## CHILD SUPPORT ENFORCEMENT

California estimated that IEVS had a significant effect on about 1.2% of its AFDC caseload. Savings due to asset matches have been pegged at $8 million while wage matching has saved an estimated $7 million per quarter.

California also found an increase in withdrawals after applicants were informed about IEVS. Additionally, they believe that recipients now report more comprehensive and precise information. Officials could not estimate the dollar amount of these "cost-avoidance" savings, but are enthusiastic about the program.

New York estimated that wage matching saved approximately $24.2 million annually; New Jersey estimated an annual saving of $13,000,000.

Question: To what extent are States identifying and recouping overpayments?

Answer: Current regulations do not require States to maintain separate records of overpayments identified or recouped through IEVS. We assume that these recoupments would not differ significantly from overpayments identified through routine case development.

Question. GAO's work has shown that during implementation most States believed that their IEVS systems would need to be automated to enhance their effectiveness. Enhanced Federal funding at 90 percent has been available for several years in the AFDC program to assist States in planning, designing, developing, and installing automated MIS. To what extent have States taken advantage of enhanced Federal funding for automating their IEVS systems?

Answer. All States developing Family Assistance Management Information (FAMIS) are required to include IEVS in order to receive

90% enhanced funding. Those States already certified for FAMIS were given an enhanced funding incentive to add it to their operating systems. Forty-three States are receiving enhanced funding; of these, thirteen are certified.

## FOSTER CARE PROGRAM

Question. The Title IV-E Independent Living program was established in response to reports of the difficulties foster care children have had in making the transition from being in care to living on their own. For example, one study showed that up to 50 percent of homeless youth seeking housing in New York City shelters had a history of foster care placement. The Administration has proposed eliminating the Independent Living program, and urging states instead to use existing authority for child welfare services, runaway and homeless youth, and the Social Services Block Grant to assist these children. If funds are redirected from other purposes such as child care and child protective services, covered by the existing authorities, to assist foster children living on their own, to what extent will the purposes of the remaining programs be underfunded and underserved?

Answer. It is the prerogative of each State to determine within broad guidelines how funds received through Federal social service programs are used. If a State wishes to increase funding of activities to assist foster children in transition to independent living, this would not necessarily reduce the combined Federal-State-local funding to child care or child protective services.

Question. Also, does the Administration believe that the level of services to help foster care youths make the transition to independent living was sufficient before this program was established?

Answer. Many of the States had begun to develop special services to foster children in the 16 and above age group, but other States had not done so. At the time the Federal program was established, the realization that this group of foster children needed extra attention, as a preventive measure, was just beginning to emerge in many parts of the country. Special programs would probably have been developed without the additional Federal initiative, but the Independent Living funds smoothed the way for a comprehensive, organized plan that would transcend spotty, uncoordinated activities and help to institutionalize such programs as a continuing part of each State's total child welfare service system.

Question. In its October 1, 1987 report, Immigration Reform: Verifying the Status of Aliens Applying for Federal Benefits (GAO/HRD-88-7), GAO recommended that HHS, and other affected Federal agencies (1) develop criteria and methodologies for granting waivers to the newly required verification system, and ensure that responsible administering entities (e.g. State AFDC agencies) develop empirical evidence needed for deciding waivers; (2) increase efforts to provide guidance to administering entities for implementing the legislated requirements; and (3) develop and implement plans to compile data and monitor the system to ensure administering entities use the most effective and economical verification means. The law also requires that each responsible Secretary (HHS, Labor, HUD, Agriculture, Education) report, by April 1, 1988, to the appropriate House and Senate committees on whether (1) the required verification methods are cost-effective and otherwise appropriate and (2) there should be waivers of the law's verification requirements. We understand that the Family Support Administration had responsibility for coordinating this report for the Department of Health and Human Services programs -- Aid To Families with Dependent Children and Medicaid -- but that a report was not submitted by April 1, 1988. The 1986 law also requires that unless granted waivers, administering entities should be using the new system--checking alien applicants' immigration status with the immigration and Naturalization Service -- no later than October 1, 1988. Why wasn't the April 1, 1988, report submitted to the appropriate congressional committee and what is the report's status? What will HHS report, e.g. is the new verification system cost-effective? (INS' Commissioner has claimed the system could save hundreds of millions of Federal benefit dollars.)

Answer. Preparation of the report, which includes both the Aid to Families with Dependent Children and Medicaid programs has been more complicated than originally planned. We have tried to produce a comprehensive report that addresses the various requirements and cost implications concerning verification of immigration status of program applicants. Our staff, assisted by INS personnel, reviewed program samples in six States to determine how current procedures compared to changes in procedures necessitated by section 121. Our efforts have been closely coordinated with staff of the companion Food Stamp program. We expect our report to be submitted in the near future.

At this time, based on the information obtained from a study of selected state verification activities, we conclude that Federal cost savings derived from the immigration status verification requirement in section 121 will modestly exceed the costs of implementing these procedures.

Question. What HHS organizational component will be responsible for ensuring that administering entities (unless granted waivers) will begin using the new system by October 1, 1988, and what does HHS plan to do when entities do not comply?

Answer. The Family Support Administration will provide overall leadership within the Department regarding implementation and operation of the increased verification requirements. Ensuring that administering entities use the new system will be charged to the programs involved: the Family Support Administration for the Aid to Families with Dependent Children program and the Health Care Financing Administration for the Medicaid program.

In instances where entities do not comply, we will first try to negotiate the issue, since we feel participation in the system is generally easy and in most cases all costs incurred by the entities are reimbursable. Our last resort would be to evoke compliance procedures under section 404 of the Social Security Act.

### WELFARE REFORM

Question. The welfare reform bills before the Congress would require States to operate education, work, and training programs for recipients of Aid to Families with Dependent Children (AFDC). Because of the relatively large number of persons that would require training under the welfare reform bills, would cost limitations result in short-term rather than intensive training for most welfare recipients?

Answer. Under the proposed legislation, we would expect a variety of services to be provided to welfare recipients, including both short-term and more intensive activities. Regardless of the availability of Federal funds, we expect States will assign many recipients to short-term activities, at least initially, since research has shown such activities to be effective for a broad range of recipients.

Question. Do States have the resources to absorb the extra costs of educating AFDC recipients who lack a high school diploma?

Answer. Funding for primary, secondary, and remedial education has always been the principal responsibility of State (and local) governments. We do not believe such costs should be shifted to the Federal government in the case of welfare recipients.

The financial burden on States will be minimized because of the Federal matching funds provided for the costs of support services for those needing additional education and because expanded participation in work program activities will reduce State costs in providing public assistance benefits.

### REFUGEE TARGETED ASSISTANCE

Question. You are requesting $34,466,000 for special refugee targeted assistance grants. Is this amount sufficient to maintain all existing grantees at current operating levels through December 1989, and still make available $10.5 million which Jackson Memorial Hospital and Dade County schools receive each year?

Answer. The $34,466,000 requested for FY 1989 is the same amount as that appropriated in FY 1988. As in FY 1988, we would plan to make $10.5 million available for Jackson Memorial Hospital and the Dade County public schools. We estimate that the remaining funds would be sufficient to continue existing targeted assistance activities at least through December 1989 and in some cases considerably beyond that date.

### COMMUNITY ACTION AGENCIES - DELAYED FUNDING

Question. There apparently have been inordinate delays in some States transmitting Federal funds under the Community Services Block Grant to local recipient agencies. Will you look into the problem of delayed funding, and let the committee know how widespread and significant it is?

Answer. We do not believe there is a problem of States inordinately delaying transmitting Community Services Block Grant (CSBG) funds to local recipient agencies. States transmit CSBG funds to sub-State entities on a schedule established by the States themselves in light of funding considerations at the State and local levels. The Office of Community Services would not want to impose a funding schedule on the States because the beginning and ending dates for sub-State work programs are a reflection of local need and State direction of the CSBG program.

Question. How long should it take for States to get funding to local Community Action Agencies, after receiving their Community Services Block Grant allocations?

Answer. It is up the States themselves to determine how much time elapses between the time the Office of Community Services awards funds to the States and the time the funds are awarded to the sub-State grantees or contractors. Under the block grant, the State is responsible for monitoring the expenditures of its grantees and/or sub-contractors and for making decisions regarding the most efficient methods of payment for services.

Question. What action can be taken against States that don't pass the money along to local agencies in a timely manner? (Background: In February, committee staff visited a rural Community Agency in Maryland, which still had not received fiscal 1988 funding, and was forced to take out a bank loan to meet the payroll.)

Answer. If a State has not violated either a statutory or regulatory requirement of the CSBG program and terminated funding to a local agency illegally, there is no authority in either the CSBG statute or the regulation governing the program that would allow the Office of Community Services to decide what is or is not a timely manner of funds disbursement by the State. Should a State terminate funding to a local agency illegally, the affected sub-State grantee or contractor may ask OCS to review the State's action and decide if the State has violated the CSBG statute. If OCS determines that the State has violated the law, the affected sub-State grantee may be funded directly by OCS until such time as the State complies with the statutory provisions.

## REFUGEES - UNSPENT FUNDS

Question. Your budget for Refugee and Entrant Assistance indicates that $3,316,000 will remain unobligated at the end of fiscal 1988, and carry forward into fiscal 1989. Why won't you obligate all the funds available to you in fiscal 1988 for refugee and entrant assistance?

Answer. The figure shown in the budget represents funds which, although reflected in the HHS budget, are administered by the State and Justice Departments. The bulk of those funds, approximately $2.3 million, are targeted to the Special Immigration Refugee Assistance program; the remaining amount is for Cuban and Haitian Processing and Domestic Assistance. Generally speaking, these amounts are not available to supplement existing HHS refugee appropriations.In actuality, we expect to obligate all FY 1988 funds appropriated to HHS for FY 1988.

Question. Is it true that because of the special nature of the refugee program the Office of Refugee Resettlement encouraged

States to provide case management services and allowed the States to charge this cost to the cash and medical assistance account?

Answer. Because Congress emphasized case management as a priority in the 1982 Amendments to the Refugee Act, we permitted States to claim certain types of case management costs against the combined grant for cash and medical assistance and State Administration (CMA grants) as an aspect of State administration.

The types of case management activities which were allowed to be claimed against the CMA grant were those which were targeted to time-eligible cash/medical assistance recipients for the purpose of helping them to obtain or retain employment.

Question. Why did you propose additional State administration cost cuts in fiscal 1989 when the case management services and costs have increased in the past three years and in fiscal 1989 you reduced the social services budget request by over 50 percent?

Answer. The budget figures are based on an estimated 51,000 arrivals in FY 1989, fewer than in previous years. Our FY 1989 budget request proposes that funding for administration continue to be approximately 12 percent of the cost of cash and medical assistance. This is both consistent with the level of funding provided by the Congress for FY 1988, and about the same percentage as in the AFDC program, and we believe it to be an appropriate figure in the refugee program as part of our overall effort to hold down costs.

Both the figure for State administration and the figure for employment services reflect the lower number of refugee arrivals projected in the budget request.

Overall, the funds requested for the refugee program take into account, first, the most important activities which must be focused on in order to help refugees become employed and self-supporting and, second, the limitations imposed by the Federal deficit situation and the bipartisan budget agreement. Within funding limitations, we consider the proposed budget policies and amounts to provide the most efficacious use of the requested resources.

Question. The Continuing Resolution was passed in December, 1987, yet the States just received notification of the State administrative costs reduction on March 4, 1988, six months into this fiscal year. Is it appropriate to ask the States to make retroactive reductions within such a compressed time frame? Why was there such a delay in notifying the States?

Answer. We began discussions with the States in early February, as soon as we became aware that administrative costs would need to be treated separately under the FY 1988 Continuing Resolution which was passed on December 22, 1987. Subsequently, on February 24, through a letter to our regional offices we asked that States be notified that we were considering ways in which to address the question of administrative funding and to allocate available funds. On March 3 we notified States of the basis on which grants would be made for the first half of the fiscal year. We did not request States to make retroactive reductions since the funds available for FY 1988 had already exceed fifty percent of the available FY 1987 level because we were under for the first 6 months a continuation of the FY 1987 level.

Question. What assumptions did you use in calculating the State administrative costs for the refugee cash and medical assistance programs in FY 1988?

Answer. In the FY 1988 request, as in the FY 1989 request, the amount proposed for State administrative costs is based on about 12 percent of the projected cash and medical assistance costs, approximately the same percentage as State administrative costs in the AFDC program.

Question. Why was the amount administrative cost amount ($33 million) that you used in FY 1988 substantially different than the FY 1987 actual costs ($42 million) for state administration?

Answer. The $33 million was based on the assumption that a regulation would be published which would limit administrative costs. Subsequently, this regulation was withdrawn.

Question. Do you see the AFDC program as the only administrative function of the State administered refugee program?

Answer. No, the components include AFDC, Medicaid, refugee cash assistance (RCA), refugee medical assistance (RMA), State supplementary payments for SSI recipients, general assistance (GA), GA medical assistance, and the program for unaccompanied minors. In addition, social services administration is encompassed in the grants to States for social services. Similarly, administrative costs associated with the targeted assistance program are met from targeted assistance funds.

Question. We understand that up to 12,000 Amerasians will be admitted into the U.S. as "immigrants", however they will be allowed to access refugee services which we assume includes cash and medical assistance. This also applies to the potential 18,000 accompanying relatives. Have you developed any budgetary plans to accommodate this potential need?

Answer. Neither the FY 1988 refugee appropriation nor the President's FY 1989 request for refugees assumed arrival of these individuals whose eligibility for refugee assistance and services results from provisions which Congress included in the FY 1988 Continuing Resolution that was enacted December 22.

Question. Will the resettlement of this population follow the normal operations of domestic resettlement?

Answer. In collaboration with the U.S. Coordinator for Refugee Affairs, the Department of State, the national voluntary refugee resettlement agencies, and States, we have initiated resettlement planning specifically for the Amerasians. The major thrust of this planning will be to resettle clusters of Amerasians in communities which will be favorable to their acceptance, adaptation, and employment.

## DISTRIBUTION OF SOCIAL SERVICES BLOCK GRANT

Question. Why can't more recent data be used as a basis for calculating the distribution of Social Services Block Grant funds?

Answer. The formula distribution for the Social Services Block Grant (SSBG) funds is not based on the December population of the previous calendar year. It is based, instead, on the most recent satisfactory data available from the Bureau of Census at the time the allotments to the States are prepared for publication in the Federal Register.

Section 2003 of the Social Security Act, the SSBG statute, requires that the State allocations must be published in the Federal Register by December 1 of the preceding fiscal year for each fiscal year. This means that fiscal year 1988 allocations must be computed and published before December 1, 1986. The purpose of this requirement is to provide States with information on funding levels prior to the beginning of the State's social services planning process for the upcoming fiscal year.

Question. Provide for the record a State-by-State comparison of fiscal 1988 allocations, based on using January data instead of December of the previous calendar year.

Answer. As prescribed in authorizing legislation, the most recent census data is used to determine State allocations. Therefore, for fiscal year 1988, the Department used August 1986 Bureau of the Census data for the SSBG State allotments published November 24, 1986 in the Federal Register (51 FR 43206).

## LOW INCOME HOME ENERGY ASSISTANCE PROGRAM (LIHEAP)

Question. LIHEAP has a weatherization component that is often administered by a different state agency than the financial assistance component. State LIHEAP agencies, however, are still responsible for reporting on the uses of the weatherization funds. These agencies have little authority over these other agencies to require reports and in many cases, these data are not being reported. Additionally, the Department of Health and Human Services and Department of Energy (DOE) weatherization programs often serve the same client population. Is FSA doing anything to increase state reporting on their uses of weatherization assistance?

Answer. On October 13, 1987, the Family Support Administration published final regulations to amend the regulations on block grant programs. The final regulations clarified that assurances in section 2605(b) of Pub. Law 97-35, including the reporting requirements, pertain to all forms of assistance provided by the States.

Question. Is FSA working with DOE to develop a national overview of Federal assistance provided to states for weatherization programs?

Answer. The Department of Health and Human Services and the Department of Energy have worked cooperatively to develop a national overview of Federal funded weatherization assistance. These projects include a planning manual for coordinating low income fuel assistance with weatherization and conservation services, a round table on preventing fraud and abuse in low income weatherization and an energy conservation weatherization education project. However, a statistical overview of Federal assistance provided to States for weatherization programs is not possible because many grantees commingle their LIHEAP weatherization funds with weatherization funds from the Department of Energy's Low Income Weatherization Assistance Program and the data submitted does not assure an unduplicated number of households receiving weatherization assistance.

Question. The Immigration Reform and Control Act of 1986 provided $1 billion a year for a 5-year period to states and localities to alleviate the impact of legalized aliens. Final regulations were issued in March 1988 for implementation of the SLIAG program. Have the states yet received any grant funds? If not, what impact is the lack of federal funding having on states' ability to assist legalized aliens?

Answer. The final rule implementing the State legalization Impact Assistance Grant (SLIAG) program was published March 10, and States have until May 16 to submit applications for FY 1988. As of May 10, we have not yet approved any applications or issued any grants. States will have access to SLIAG funds as soon as their applications are approved. We do not believe this timetable will have an adverse impact on the ability of States to assist eligible legalized aliens.

SLIAG funds may be used to reimburse State and local government costs associated with providing public assistance and public health services to eligible legalized aliens, but only those services that are generally available to the population of the State or locality. (See section 204(j) of the Immigration Reform and Control Act of 1986 (IRCA).) Thus, as a practical matter, public assistance and public health costs for which SLIAG funds may be used are costs that would have been incurred whether or not SLIAG had been created. The State may reimburse allowable expenditures retroactive to October 1, 1987, and in the case of public health, retroactive to May 5, 1987, the beginning of the legalization program. In addition, any funds not obligated this year may be carried forward for use in subsequent fiscal years, up to September 30, 1994. Therefore, we believe that States' ability to provide public assistance and public health services to eligible legalized aliens will be unaffected by the date on which SLIAG funds become available.

The third allowable use of SLIAG funds is educational services for eligible legalized aliens. States may use SLIAG funds to start new educational programs for eligible legalized aliens and may reimburse allowable State and local costs retroactively to October 1, 1987. SLIAG funds are available for use through September 30, 1994, and educational services funded through SLIAG may be provided to an alien any time during the five-year period after the alien obtains legal temporary residents status. Thus, we believe States will have ample time to provide educational services to eligible legalized aliens.

## HEAD START PROGRAMS FOR WORKING PARENTS

Question. It has been suggested that Head Start projects lengthen their program year and extend their hours, in order to better meet the needs of working parents. How many Head Start projects currently offer full-day services for working parents?

Answer. Approximately 190 of 1900 Head Start programs offer full day services to working parents. These programs have an enrollment of slightly over 40,000 children.

Question. How much more would it cost for all Head Start projects to offer full-day, full-year services?

Answer. If we were to assume that all currently enrolled Head Start children needed full-day, full-year services, this would cost an estimated $1,245,000,000 more than Head Start's current appropriation of $1,206,324,000. However, we would expect that many Head Start parents would not want their children enrolled in a full-day, full-year program, either because they did not work, or had alternative child care arrangements. Thus, the $1,245 billion estimate above would need to be reduced by whatever proportion of Head Start children would not need to receive full-day full-year services. We do not know at this time what proportion this might be.

Question. How practical an idea is it to convert most Head Start projects to full-day, year-round operations?

Answer. Head Start is primarily a child development program. We appreciate that many Head Start parents need child care services and indeed some of our programs do offer services for extended hours. However, we feel that for Head Start the focus should be child development and that an increase in funding would be better spent to either improve the quality of the current program or to increase the number of children and families we are able to serve, rather than extending the hours and days of operation for our current enrollees. We encourage Head Start programs to coordinate with other social service providers in the community, or to explore alternate funding sources, so that working Head Start parents in need of full-day care could receive such care without compromising Head Start's primary mission of providing comprehensive child development services to low income children and families.

## GENERIC APPROPRIATION

Question. You are no longer requesting consolidation of 26 Human Development programs into a "generic" appropriation, but instead are asking Congress to merge funding for several research, training, and demonstration activities. Does this latest proposal represent a rethinking of how to better administer human development programs, or is it viewed as more likely to be acceptable to Congress?

Answer. The request for a single line item for research, training, and demonstration programs is made to focus attention on the total committment to these types of activities.

## DISCRETIONARY CONSOLIDATION

Question. If you are granted authority to consolidate several research and demonstration activities, will separate accounting still be maintained to identify sources of funding for each piece of legislation, such as the Child Abuse Prevention and Treatment Act and The Developmental Disabilities Act?

Answer. Separate funding and accounting will be maintained for each of the categorical programs included in the single line item request.

Question. How much would you spend on each component of the items to be consolidated, such as child welfare training and adoption opportunities?

Answer. The following amounts would be spent for each of the programs:

| | |
|---|---|
| Child Abuse and Neglect | $13,306,000 |
| Child Welfare Research and Demonstration | 13,244,000 |
| Child Welfare Training | 3,660,000 |
| Adoption Opportunities | 4,787,000 |
| Aging Discretionary Activities | 23,935,000 |
| Developmental Disabilities Special Projects and University Affiliated Programs | 15,318,000 |
| Social Services Research | 2,400,000 |
| Total | $76,650,000 |

## IN-HOME SERVICES FOR FRAIL ELDERLY

Question. Last year Congress provided start-up funding of $4,787,000 for the newly authorized Older Americans Act program of in-home services for the frail elderly.

— How do you expect to implement a meaningful program in fiscal 1989 with your budget request to keep funding at the start-up level of $4,787,000?

Answer. The Department's FY 1989 request for funds for Title III-D services is consistent with the Bipartisan Budget Agreement. We believe that such a request can contribute significantly to the President's efforts to effect major reductions in the Federal budget deficit while, at the same time, providing additional resources (beyond those available under Title III, Part B) to the States for in-home services activities.

Question. Last year Congress provided start-up funding of $4,787,000 for the newly authorized Older Americans Act program of in-home services for the frail elderly.

-- Is there any doubt that the fully authorized level of $26,250,000 could be put to effective use?

Answer. The Department is confident that the States will effectively use the funds we are requesting under Title III, Part D, for in-home services for frail older persons. Further, we know that, as States identify priority needs for additional in-home services, they will allocate as much of their Title III, Part B (Supportive Services and Senior Centers) funds as are required to meet those needs. States and communities have repeatedly demonstrated their capacity to target Older Americans Act resources on priority service needs and I am certain they will continue to provide funds for effective in-home services efforts.

## OLDER AMERICANS OMBUDSMAN SERVICES

Question. Last fall's revisions to the Older Americans Act authorized $20,000,000 for home care ombudsman services, and $957,000 was appropriated to begin implementing the program.

-- Why is only $957,000 being requested for fiscal 1989, the first full year of operations under this new authorization?

Answer. As in the case of other programs authorized under the Older Americans Act, the Administration has determined that basing the FY 1989 budget request for ombudsman program at the FY 1988 level is consistent with the Bipartisan Budget Agreement's. I would also like to note in this regard that States have wide latitude in allocating Title III, Part B (Supportive Services and Senior Centers) funds to address priority needs, including the need for ombudsman services. States have effectively used Title III-B resources in support of the ombudsman program in the past and I am certain they will continue to do so.

Question. To what extent are you monitoring expenditures to make sure these funds are indeed used for home care ombudsman activities?

Answer. Based on the advice of our Department's General Counsel, we determined to treat the $957,000 as part of the Title III Part B (supportive services and senior centers) appropriation under the authorizing authority in section 303(a)(1). Accordingly, we allotted the funds to States under that authority without any further limitation on the use of the funds by States. Since the funds were not earmarked specifically for ombudsman activities, States are free to use the funds for any activity authorized under section 303(a)(1), including but not limited to ombudsman activities. We will monitor the overall use by States of funds received under section 303(a)(1).

## SOCIAL SERVICES BLOCK GRANT STATE REPORTING

Question. Money provided to the states under the Title XX Social Services Block Grant is often mixed with State and local monies to fund a wide variety of programs for the elderly, children, and the disabled. Do you think it would be useful to get a better picture of what the Block Grant does by requiring States to report in detail on the number of individuals served, the types of services offered, and the criteria used by States to determine if individuals qualify for programs funded by the Social Services Block Grant?

Answer. The basic purpose of the block grant legislation was to reduce the considerable information collection burden previously required and to provide States with maximum flexibility in the design of their social service programs.

Many States are taking advantage of this additional flexibility to make improvements in State planning and budgeting processes and to better integrate block grant funds with other State social services program funding.

Block grant funds represent only a portion, albeit a significant portion, of the total dollars used to support State social services programs. One effect of coordination and integration of State programs is to negate the specific character of the Title XX Social Services Block Grant (SSBG) as a separate program for which a separate data collection system must be kept.

The Department has required States to report only that information which is statutorily mandated. Therefore, given the changes in State planning and coordination of social services over the past seven years, we believe the cost of requiring States to report, in detail, SSBG information on individuals served, services, and eligibility would outweigh the benefits to be obtained.

Question. Would an amendment to Section 2006 of Title XX of the Social Security Act to include detailed reporting be required to implement such standards, or could Health and Human Services adopt them by regulation?

Answer. If such additional information was determined to be necessary, we would explore administrative measures to collect such information.

## DEVELOPMENTAL DISABILITIES REAUTHORIZATION

Question. Last year, Congress passed legislation to renew and expand activities authorized under the Developmental Disabilities Assistance and Bill of Rights Act. How do you expect to meet all the requirements of the new law while freezing appropriations at FY 1988 levels?

Answer. The appropriation for FY 1988, under the Developmental Disabilities Assistance and Bill of Rights Act, represented a $9.180 million increase over the appropriation for FY 1987, an 11.0% increase. The developmental disabilities State Planning Councils are doing an extremely good job in influencing state program policies to enhance the quality and availability of services to persons with developmental disabilities. This is especially true with respect to the new requirements under the law, which the Department of Health and Human Services feels can be effectively advanced by the better utilization of existing national resources.

Question. Last year, Congress passed legislation to renew and expand activities authorized under the Developmental Disabilities Assistance and Bill of Rights Act. Could you effectively utilize the authorized amount of $69,900,000 in FY 1989, instead of your $58,401,000 budget request for basic State grants?

Answer. We believe we and the state agencies together can effectively plan, manage, and run the basic program within existing funding levels to best serve the community of persons with developmental disabilities.

Question. Last year, Congress passed legislation to renew and expand activities authorized under the Developmental Disabilities Assistance and Bill of Rights Act. Would there be any difficulty utilizing the $22,000,000 authorized level for protection and advocacy, instead of the $19,148,000 budget request?

Answer. The 1988 appropriation represented a $3.648 million increase over FY 1987. We believe we together with the state protection and advocacy systems, now strengthened by additional authorities under the law and additional state resources, can effectively and efficiently plan, manage, and run the protection and advocacy program within existing funding levels to best serve the community of persons with developmental disabilities.

Question. Your budget maintains the FY 1988 level of $15,318,000 for Developmental Disabilities Projects of National Significance and University Affiliated Programs, for which $18,750,000 is authorized in FY 1989. How many University Affiliated Programs would be funded in FY 1989 at the authorized level, compared to your budget request?

Answer. The Department of Health and Human Services expects that four new University Affiliated Programs or Satellites, depending on the results of fiscal 1988 feasibility studies, will be funded in FY 1989 at the requested budget level. An increase in appropriation over the requested level would not necessary result in funding additional centers.

Question. Your budget maintains the FY 1988 level of $15,318,000 for Developmental Disabilities Projects of National Significance and University Affiliated Programs, for which $18,750,000 is authorized in FY 1989. What is your ultimate goal for expansion beyond the current level of 36 University Affiliated Programs and 6 Satellite Center grantees?

Answer: The Department of Health and Human Services' goal is to fund 4 new University Affiliated Programs or Satellites per year, pending results from feasibility studies. Consequently, by the end of FY 1989 our goal is to fund 8 new University Affiliated Programs or Satellites in states currently unserved by a University Affiliated Program funded by the Department of Health and Human Services.

## CHILD CARE FOR HANDICAPPED CHILDREN AND CRISIS NURSERIES

Question. Last year Congress provided $4.8 million for start-up of the Temporary Child Care for Handicapped Children and Crisis Nurseries Act of 1986. What is the status of implementing this program, and what kinds of activities are being funded?

Answer. Funds were first appropriated for this program in FY 1988. A notice to the Governors of all States and other eligible jurisdictions requesting grant applications for these funds is currently being prepared. Grants will be awarded by September 30, 1988.

Question. How much is budgeted for this program in fiscal 1989, as part of your proposal to consolidate several children's activities?

Answer. The authorization for this legislation expires on September 30, 1988. The administration has added $4.787 million to its appropriation request for Child Welfare Research and Demonstration funds, under which authority activities covered by the Temporary Child Care legislation can be carried out.

## COMMUNITY PARTNERSHIP DEMONSTRATION GRANTS

Question. Last year, congress funded the second round of Community Partnership Demonstration Grants at $2.9 million. When do you expect to award these grants?

Answer. Grant awards will be announced between September 15 and 19, and will be mailed to recipients on September 21, 1988.

Question. How many applications do you anticipate, and how many projects do you expect to fund?

Answer. We expect to receive around 100 applications and will fund between nine and twelve of the top ranked applications.

Question. What have been the results so far with the first round of grants made with the $1 million appropriated in fiscal 1987?

Answer. In Fiscal Year 1987, five of 94 applicants were awarded two-year grants averaging $200,000 each. Two of the grants were for micro-entrepreneurship projects in rural areas in New York and Vermont, while the remaining three were for projects testing new approaches to the problem of chronic dependency among female-headed welfare families in Phoenix, Arizona, Fargo, North Dakota, Hiawatha, Kansas and Yamhill County, Oregon; Yamhill and Hiawatha shared a grant. Since the Demonstration Partnership is a new program, its results will not be evident until late in 1989. At that time, the Department will assess project results and disseminate any successful models to the States and the entire community action agency network.

## INDEPENDENT LIVING PROGRAM

Question. You've had two years of experience implementing the Independent Living Program, designed to help older teens make the transition from Foster Care to independent living. What type of services have been funded by this program, and how successful have they been?

Answer. Expenditures in State Independent Living programs must be related to the specific purpose of the Independent Living Initiatives in section 477 of the Social Security Act. Activities may include, but are not limited to, the following:

(1) Counseling and other similar assistance related to educational and vocational training, preparation for a General Equivalency Diploma (GED) or higher education, job readiness, job research assistance and placement programs;

(2) Counseling and instruction in basic living skills, such as: money management, home management, consumer skills, parenting, health care, access to community resources, transportation, housing options and location;

(3) Individual and group counseling, workshops and conferences for improved self-esteem and self-confidence, interpersonal and social skills training and development;

(4) Coordination with other components of the State's independent living program, e.g., supervised practice living, and establishment of linkages with Federal and State and local organizations related to education, employment, training, housing, etc.

Reports on progress for the first year have not provided information about successful outcomes but a report due this Summer to Congress will provide more information.

Question. Why haven't you sought renewal of the authorizing legislation, which expires in FY 1989?

Answer. The Administration believes that State agencies have resources within their current programs which could cover the needs of older adolescent foster children without additional Federal funds. Specifically, states can use existing authorities for Foster Care, Child Welfare Services, Runaway and Homeless Youth, and the $2.7 billion Social Services Block Grant for these purposes.

Question. How do you expect States to absorb the loss of this $45 million appropriation within existing social services funding, which has not kept pace with inflation in recent years?

Answer. There are several ways in which State agencies may continue the Independent Living Initiatives after the Federal funds have been expended:

(1) The development of a case plan for each child age 16 or over, to include a written description of the programs and services which will help the child prepare for the transition from foster care to independent living, is an activity which may be claimed as an administrative cost under section 474 of Title IV-E at a 50% Federal match.

(2) The State agency, through integration and coordination of

services otherwise available to participants, may be able to secure slots in existing courses, such as educational services to achieve a high school diploma or its equivalent or vocational training available through community colleges, whereby all persons in the Independent Living Initiative population can be assisted in reaching their individual educational and training goals.

(3) Each State's share of the $45 million for fiscal years 1987 and 1988 will be spent for a variety of activities and materials, many of which will have a "shelf life" beyond the two year period. For example, training materials related to daily living skills, budgeting, locating and maintaining housing and career planning can be utilized for new groups of youth who reach age 16 after the Federal funds have been used.

(4) Foster parent education may be expanded to provide intensive training to develop and enhance skills in assessing the future needs of older foster children and in acting as mentors to the children in their care in preparing them for independence. Section 477 of title IV-E funds could be used during the two year Federal funding period to pay for specialized training materials for continued use in future years. Foster parents education and training is also allowable as a IV-E administrative cost.

(5) Individual and group counseling is a service that has been provided in many States through the use of title IV-B or title XX Social Services Block Grant funds.

(6) Staff hired or contractors employed during the two-year period can provide specialized training to permanent staff to aid them in a continuing role as advisors to adolescent youth in their caseloads to prepare them for adulthood.

(7) State child welfare agencies can utilize short-term section 477 funds to develop specialized group living facilities for transitional living, under the supervision of fulltime staff trained to provide foster care to small Independent Living populations during the last six months or year prior to emancipation. Such homes would be licensed as foster homes or group homes, either under contract with private, nonprofit agencies or as agency group homes, and would provide opportunity for experiences, under supervision, in independent living activities. The costs of such care would be allowable for Federal Financial Participation under Title IV-E.

## NATIONAL YOUTH SPORTS PROGRAM

Question. You are proposing to terminate the National Youth Sports Program, which is currently funded at $6,319,000. What is your assessment of the value of this program, which provides recreational opportunities for about 58,000 disadvantaged youth annually?

Answer. The Department is not proposing to eliminate funding for the National Youth Sports Program (NYSP) during FY 1989. During the last three years this program has provided approximately 160,000 poor and disadvantaged youths with services. These include medical screening, sports skills and physical fitness instructions, nutritional education and USDA meals in an effort to acquaint disadvantaged youth with opportunities which exist in our society.

Question. What is your rationale for proposing elimination of Federal funding for the National Youth Sports Program?

Answer. The Department is not proposing to eliminate funding for the National Youth Sports Program (NYSP) during FY 1989. We expect to provide to the NYSP a proportionate share of the funds requested for the CSBG Discretionary Program in FY 1989.

## STATE FUNDING

Question. When are states awaiting reimbursements for unpaid, but approved and processed claims for foster care likely to receive the first influx of dollars from those claims?

Answer. As part of the FY 1989 budget request, the Administration has asked for funds to pay back claims for Title IV-E Foster Care. If the funds are appropriated, they will be awarded to States shortly after they are made available in FY 1989.

## FOSTER CARE - PROGRAM PROBLEMS

Question. The intent of P.L. 96-272 was to strengthen families and to re-unify them rather than to have children languish unnecessarily in foster care. Soon after implementation, foster care caseloads fell, and now they are again on the rise. The media has indicted foster parents for abusing children, and caseworkers for being unresponsive. Staff, who are often untrained and inexperienced, are faced with high caseloads and with working with families with few of the ancillary supports and resources that are needed. What plans does Office of Human Development Services (OHDS) have to strengthen the foster care system by setting staffing standards and requirements so that agencies and workers have the skill and ability to work in a family centered way with the multi-problem families that are represented in the foster care system?

Answer. We do not have any plans to set staffing standards and requirements for State and local agencies and workers. States have to make the final determination of how best to use their resources to meet child welfare needs. However, the Office of Human Development Services, through its discretionary funding resources, places considerable emphasis on family centered approaches to work with multi problem families, through the funding of national resource centers, development of training and technical assistance programs and materials and funding of demonstration programs.

The National Resource Center on Family Based services at the University of Iowa has, for a number of years, provided training and/or technical assistance to over 25 States on the restructuring of their child welfare services to focus on up front services to keep the family intact. The Center has developed a number of resources for States to use in establishing these programs, including: Family Centered Services, A Model for Child Welfare Agencies, a handbook for public agencies; Annotated Directory of Selected Family Based Service Programs; and training materials.

OHDS also has funded 13 demonstration grants to States to enable them to upgrade, improve or develop family based services. In FY 1988, HDS expects to fund a research evaluation of intensive family based services.

The National Resource Center for Foster and Residential Care offers a wide range of training and program assessment services to public and voluntary agencies providing foster and residential care, with a special emphasis on services to minority populations. This Center is developing a training program which focuses on developing a team approach to reunification, involving foster parents, workers and natural parents in achieving reunification of children with their families. This program has been evaluated and will be marketed nation wide.

In addition, since 1985, we have funded 14 grants focusing on the development of specialized recruitment, training and support programs for foster families dealing with special needs children. A key element of all of these grants is viewing foster care as temporary substitute care in a program for reunification of children with their families, with special attention on how agencies, foster families and birth families of children in their care can work together to stabilize the situation so children can return to their families.

Also, through the Child Welfare Training grant program over the past several years we have funded over 200 traineeship and inservice training grants to schools of social workers and Indian Colleges, to expand the number of professionally educated and trained individuals who provide services in the public child welfare system.

## SAFEGUARDS AGAINST CHILD ABUSE

Question. What are the strategies in OHDS to work together with other organizations and experts to have sufficient resources and knowledge to develop safeguards against child abuse in out of home care?

Answer. The strategies which we have used to develop safeguards in out of home foster care include:

(1) The development of specialized recruitment, training and support programs for foster families dealing with special needs children. Since 1985, we have awarded demonstration grants to accomplish the following:

- development of joint recruitment programs among child welfare and developmentally disabled and mental retardation agencies, for specialized homes;

- development of a program of therapeutic foster homes where foster parents are trained to handle children with special emotional and behavioral needs; and

- development of cost effective, comprehensive strategies to address a community's foster care population, including training of workers, supervisors and foster parents; and the development of a variety of support strategies such as respite care, and cluster homes, which provide mutual support and coordination with parents and advocacy groups that serve specialized or developmentally disabled populations.

(2) Providing ongoing opportunities since FY 1984 for over 20 States and additional tribes to update and restructure their licensing programs, taking into account an improved structure, process and staffing for approving and monitoring the licensing of foster family homes, group homes and child care institutions.

(3) Implementing legislative changes made by the Child Abuse Amendments of 1984 concerning the definition of persons responsible for the child's welfare. This definition was broadened to include any employee of a residential facility or any staff person providing out-of-home care.

## FOSTER CARE BACK CLAIMS OWED TO STATES

Question. Your budget includes $108,041,000 for foster care and adoption assistance prior year claims. Is this enough to bring prior year claims up to date?

Answer. We estimate that this amount will enable us to reimburse States for prior year claims through FY 1986.

Question. What is the status of disagreements with the States over the level of and timeliness of back claims?

Answer. We have worked with States on an individual basis to reach agreement on the amount of undisputed funds that have not been reimbursed. We are also working with the American Public Welfare Association on a method by which an amount might be determined for all States as to the undisputed amount owed. Regarding timeliness, we must work through the appropriations process so that we have available the funds to satisfy allowable claims.

## REFUGEE RESETTLEMENT

Question. Unlike previous years, your Department's Justifications of Appropriations Estimates for Committee on Appropriations for FY 1989 does not include, in the "Summary of Changes" section, any cost estimates for changes in unit costs of social services and preventive health or estimates for increases in average cash and medical assistance benefit costs. What are the estimated percentage changes in unit costs for social services and preventive health and in average cash and medical assistance benefit costs for FY 1989? What is the estimated percentage change in state administration costs per case in FY 1989?

Answer. Average costs per refugee recipient of cash and medical assistance benefits are expected to increase by approximately 4.8 percent in FY 1989, from an estimated average cost of $2,445 in FY 1988 to $2,562 in FY 1989. State administration costs per recipient are currently estimated at $314 in FY 1989, compared with an estimated cost of $310 per recipient in FY 1988, an increased of 1.3 percent. The reduction in budgeted expenditures for providing preventive health services reflects a shifting of such costs to the Medicaid and Refugee Medical Assistance (RMA) programs, rather than a reduction in the unit cost of such services performed or provided. Similarly, the reduction in expenditures for social services to enhance employment prospects and opportunities for refugees does not represent a reduction in the unit cost of services rendered, but rather is intended to achieve a more effective targeting of the social services to be provided.

Question. The Office of Refugee Resettlement's (ORR) FY 1989 budget request assumes a $35,694,000 cut in social services funding "due to declining annual equivalent populations and regulatory limits on the period of refugee eligibility for services." How much of the cut is due to the decline in population size? Please describe the proposed regulatory limits.

Answer. The Refugee appropriations for several years prior to 1988 were made through continuing resolutions, which maintained high levels for social/employment services despite declines in refugee admissions. Therefore, the current request based on actual expected admissions of 51,000 refugees, simply brings the funds in line with the numbers of people entering the U.S. The proposed regulatory limits, however, are not being pursued.

Question. Only $3,000,000 is being requested for preventive health activities in FY 1989, compared to appropriation levels of $5,840,000 in FY 1988 and $8,039,000 in FY 1987. What were the total amounts of preventive health grants awards to state and local health agencies in FY 1987 and FY 1988, respectively? How much would be awarded to states and localities in FY 1989?

Answer. The total amount of preventive health funds awarded to 40 State and 6 local health agencies for health assessment grants in FY 1987 was $5.4 million. In FY 1988, $3.6 million is being allocated. It is estimated that $800,000 will be available for such grants in FY 1989.Other State preventive health costs will be covered through Medicaid and refugee medical assistance.

Question. I understand that ORR's FY 1989 budget request assumes that period of special refugee cash assistance (RCA) and refugee medical assistance (RMA) would be reduced from the current 18 months to 12 months. Assuming an 18-month eligibility period, what would be the estimated average monthly number of RCA recipients in FY 1989? How much more would it cost to fund an 18-month period than a 12-month period in FY 1989?

Answer. ORR's FY 1989 budget request assumes that refugees would be entitled to 12 months of special cash and medical assistance (RCA/RMA) and 12 months of general assistance (cash and medical) for a maximum eligibility period of 24 months. If, as proposed, the eligibility period for special refugee assistance would be increased to 18 months (and that for general assistance reduced to 6 months), the average monthly number of RCA recipients would be expected to rise by approximately 3,200 and the net increase in total program costs would amount to an estimated $6.0 million.

Question. For purposes of calculating cash and medical assistance costs, what does your Department assume to be the average monthly number of refugees and entrants in the U.S. in FY 1989 who have been in the U.S. for: 12 months or less; 18 months or less; 24 months or less; 31 months or less; 36 months or less?

Answer. The following table provides data on the estimated average monthly number of time-eligible refugees and entrants in the U.S. in FY 1989 for various time-eligible periods.

| Time-eligible period (months) | Average Monthly Number of Refugees |
|---|---|
| 12 months or less | 63,486 |
| 18 months or less | 95,501 |
| 24 months or less | 127,562 |
| 31 months or less | 161,101 |
| 36 months or less | 185,719 |

Question. For FY 1989, what does your Department assume to be the cash assistance dependency rate in the U.S. for refugees who have been in the U.S. for: 12 months or less; 13 to 18 months; 19 to 24 months; 25 to 31 months; or 32 to 36 months?

Answer. The most recent information available on this subject resulted from a national sample survey of Southeast Asian refugees conducted in the fall of 1985 and was included in ORR'S FY 1985 Annual Report to the Congress. The survey showed the following percentages of refugees in households receiving cash assistance, by length of residence in the U.S.:

| Months | Percentage In Cash Assistance Households |
|---|---|
| 0-6 | 61.4% |
| 7-12 | 49.2 |
| 13-18 | 54.5 |
| 19-24 | 62.8 |
| 25-30 | 56.3 |
| 31-36 | 51.4 |
| 37-60 | 50.3 |

Question. For FY 1989, what do you estimate to be the cost of reimbursing 100 percent of states' cash and medical assistance costs for refugees who have been in the U.S. for: 24 months or less; 31 months or less; or 36 months or less? (Note: assume that RCA and RMA benefits will continue to be provided to refugees who are not categorically eligible during their initial 18 months in the U.S.)

Answer. The budget for FY 1989 requests $182,189,000 to reimburse States for providing cash and medical assistance benefits to eligible refugees for up to 24 months. If the subsidy period were increased to 31 months, an estimated $30.0 million in additional assistance costs would be incurred. With a 36 month program of subsidies, State assistance costs would be expected to increase by an estimated $48.0 million over the current budget request.

Question. For FY 1989, what do you estimate to be the cost of reimbursing 100 percent of state administrative costs for refugees who have been in the U.S. for: 24 months or less; 31 months or less; or 36 months or less? Assume no changes in policy.

Answer. Assuming no change in policy (24 months of eligibility for cash and medical assistance to eligible refugees), the budget for FY 1989 requests $21,569,000 to reimburse States for program administrative costs. If the eligibility period were increased to 31 months, an estimated $3.6 million in additional State administrative costs would be incurred. With a 36 months program of subsidies, state administrative costs would be expected to increase by an estimated $6.9 million over the current budget request.

Question. Please provide the Committee with the following expenditure data for FY 1987 relating to cash and medical assistance and state administration costs by category of aid. Use estimates for those categories for which actual data are unavailable.

Answer. The following table provides actual expenditure data for cash and medical assistance by category of aid, as well as total state program costs. Data are not available to identify separately administration costs by category of aid.

REFUGEE RESETTLEMENT

| Category of Aid | Total Assistance Expenditures | Total Administrative Expenditures 1/ |
|---|---|---|
| AFDC | $ 54,014,000 | $ |
| Refugee Cash Assistance (RCA) | 55,306,000 | |
| SSI-State Supplements | 11,139,000 | |
| General Assistance - Cash | 7,417,000 | NA |
| Total Cash Aid | $127,876,000 | $ |

| Category of Aid | Total Assistance Expenditures | Total Administrative Expenditures 1/ |
|---|---|---|
| Medicaid | $ 27,975,000 | $ |
| Refugee Medical Assistance (RMA) | 27,889,000 | |
| General Assistance - Medical | 2,184,000 | NA |
| Total Medical Aid | $ 58,048,000 | $ |
| State Program Administration | $ 41,880,000 | $ 41,880,000 |

1/ Administrative expenses cannot readily be broken down into the requested separate categories of aid.

Question. For each of the above categories of aid (e.g., AFDC, RCA or Medicaid), what was the actual (or estimated) average monthly number of time-eligible refugee recipients in FY 1987?

Answer. The following table provides data on the average monthly number of time-eligible refugee recipients in FY 1987.

| Program Category | Average Monthly Number of Recipients |
|---|---|
| Cash Assistance: | |
| AFDC | 59,514,000 |
| Refugee Cash Assistance (RCA) | 24,279,000 |
| SSI-State Supplements | 4,300,000 |
| General Assistance-Cash | 5,891,000 |
| Recipients of Cash Assistance | 93,984,000 |
| Medical Assistance: | |
| Medicaid | 59,514,000 |
| Refugee Medical Assistance (RMA) | 24,279,000 |
| General Assistance-Medical | 5,891,000 |
| Recipients of Medical Assistance | 89,684,000 |

## MEDICAL LIABILITY LEGISLATION

Question. We understand that your office has developed a model for medical liability legislation, and that you have provided it to several States for their consideration. How many States have adopted medical liability legislation, based on your model?

Answer. The Secretary's initiative to encourage State tort reform consists of two integral activities: (1) dissemination of the report from the Secretary's Task Force on Medical Liability and Malpractice to the Governors, State legislative leadership and professional organizations which represent the constituencies affected, and (2) dissemination of a model statute which would assist states in addressing tort reform in a comprehensive manner. The Task Force Report was completed and initially disseminated in August 1987. The model legislation, which was drafted in conjunction with the Department of Justice, was completed and disseminated in late December 1987.

A number of states utilized the Task Force Report for the development of legislation in the fall of 1987; others used the report and model bill during 1988 legislative sessions. Prior to 1987, most states had addressed tort reform on a piecemeal basis; therefore, some of the provisions of the proposed act were already in place in some states, while others were not. The model bill is thus an effort to assist both those states which have not addressed the issue comprehensively and those states which are in the process of amending their existing statutes.

Twenty-six states have acknowledged the use and/or adoption of either specific Task Force recommendations on tort reform or the model legislation. Many 1988 legislative sessions are just now ending, so a complete evaluation of what has been accomplished in this year's sessions is not yet available. However, we are aware of at least eight states which have adopted either tort reform legislation consistent with recommendations from the report or model legislation. Action is also pending in at least five others (two states have addressed the issues comprehensively). We are advised that at least eight states will have interim reviews of tort reform legislation during 1988, and we anticipate the use of the model legislation and Task Force Report as a basis for their deliberations. While 1988 sessions were limited to budget matters in many states, 1989 is clearly a target year for this issue to be addressed.

## QUESTIONS SUBMITTED BY SENATOR LAWTON CHILES

### REFUGEE ADMISSIONS - UNBUDGETED

Question. There appears to be a good possibility that the fiscal 1989 refugee population entering the country could be as much as 47,500 higher than the 51,000 level assumed in your budget request. First of all, your budget does not account for 17,500 refugees in the official State Department ceiling estimate of 68,500. Second, it does not support the 15,000 additional Armenians and other East Europeans likely to be admitted on an emergency basis later this year. Thirdly, it does not accommodate a possible 15,000 increase in Amerasians, who would be eligible for refugee assistance under a provision added to the fiscal 1988 continuing resolution. Is this assessment an accurate update of events that have developed since your fiscal 1989 refugee budget was formulated?

Answer. Yes, those figures coincide with our current expectation of arrivals. However, as you note, the 15,000 Armenians and East Europeans would be expected to arrive in FY 1988, the expectation for FY 1989 arrivals is 32,500 higher than the 51,000 budget level. The additional FY 1988 arrivals will of course impact FY 1989 costs.

Question. How much more would have to be added to your budget, based on 31 months of cash and medical assistance, if as many as 47,500 additional refugee admissions materialize?

Answer. It is estimated that the addition of 47,500 additional refugees would increase our FY 1989 budget request by $114.8 million to an amount of $318.6 million for cash and medical assistance and State administration.

Question. Will you seek a budget amendment from OMB to cover the extra refugee resettlement costs?

Answer. Discussions are underway between HHS and OMB on strategies for covering the extra refugee resettlement costs.

### REFUGEES - EMERGENCY ASSISTANCE

Question. In an April 6, 1988, report to Congress, the U.S. Refugee Coordinator, Jonathan Moore, explained the need to admit up to 15,000 additional refugees before the end of fiscal year 1988. He estimated the additional costs for the balance of this fiscal year could be up to $9.6 million for cash and medical assistance, State administration, and preventive health programs. How do you plan to meet these additional costs for emergency refugee assistance without requesting a supplemental.

Answer. We are uncertain of the potential FY 1988 cost-impact of the additional 15,000 refugees. This will depend largely on when these refugees arrive, since the later in the fiscal year that the original ceiling of 68,500 is exceeded, the less will be the FY 1988 impact of the additional arrivals. At this time we believe Fy 1988 costs from these 15,000 will be minimal. If additional FY 1988 costs occur beyond our expectations under the original ceiling, we plan to permit the States to absorb those costs rather than to seek additional funds.

Question. Is it fair to force States to pay for refugee resettlement costs that result from Federal actions?

Answer. We believe it is important that an appropriate balance be achieved between those initial costs following a refugee's arrival for which special Federal funding should be provided and those longer term costs which should be met in the same manner as for other residents of our Nation, States, and communities. Over time, the majority of refugees become self-supporting members of our society, paying Federal, State, and local taxes on the same basis as other residents of the communities in which they live; thus long-term special Federal funding is difficult to justify. Our budget request proposes a refugee's first 24 months in the U.S. as the appropriate time for cash and medical assistance to be fully federally funded. Eligible Refugees would continue to receive benefits after their first 24 months, at which time the Federal government wold fund the normal Federal share and States would begin funding the normal State share.

## LIHEAP - LOW STATE PRIORITY

Question. Your budget justification indicates that of $1.7 billion in oil overcharge funds so far designated by States, only $275 million, or 16 percent, has been designated for the Low-Income Home Energy Assistance Program (LIHEAP). Why are States earmarking such a small percentage of oil overcharge funds for the Low-Income Home Energy Assistance Program?

Answer. The States, like the Federal government, must determine funding priorities based on their assessment of the needs of their constituents. We assume that the States are taking into account many of the same factors that the Federal government is considering in determining its budget priorities. Specifically, these factors include the stabilization of energy prices, the other Federal, State and private programs providing energy assistance and a continuing decline in the percent of annual income that low income households expend for home heating.

Question. How much flexibility do the States have to utilize a greater percentage of oil overcharge funds for Low-Income Home Energy Assistance.

Answer. Because LIHEAP is a block grant which does not require "approval" of plans, it is easier for the States to designate oil overcharge funds for LIHEAP than it is for the States to designate oil overcharge fund for the DOE energy conservation programs or other energy-related restitution programs. For example, the State Energy Conservation Program (SECP) requires a Federal/State cooperative effort with a 20% State matching requirement and the

Institutional Conservation Program (ICP) requires a 50% grantee matching requirement. The amount of flexibility that the States have to redesignate unexpended oil overcharge funds to LIHEAP depends upon whether the State delegates responsibility over allocation of oil overcharge funds to the Governor, State Legislature or State Energy Office.

Question. Of the remaining $1.3 billion in undesignated oil overcharge funds available to the States, how much do you reasonably expect could be used for Low-Income Home Energy Assistance this winter? (Background: GAO reports that only 12 percent of the recent "Stripper Well" oil overcharge distributions have been used for LIHEAP -- it appears some States are using the funds for roads and potholes.)

Answer. Based on the percentage of oil overcharge funds that have been allocated to LIHEAP in past fiscal years, we estimate that 27% of the remaining Exxon funds will be allocated to LIHEAP, or $270,000,000; 10% of the remaining Stripper Well funds, or $33,000,000; and 10% of the future Stripper Well distribution in FY89 (i.e., Texaco) $25,000,000. Therefore, we estimate that if States continue to allocate the same percentage of oil overcharge funds to LIHEAP as they have in the past, then $328 million in oil overcharge funds could be allocated for energy assistance for the winter of 1988-89. Additional funds may be allocated for future years; some States have already made such allocations for future years.

## HEAD START

Question. You propose "freezing" Head Start spending in FY 1989 at last year's level of $1.2 billion -- which is $48 million below the level the Congressional Budget Office says is needed to maintain current services. How do you realistically expect to serve the same number of children, without a reduction in service quality, with no more money than FY 1988?

Answer. Head Start has received substantial funding increases in 4 of the last 5 years. We have used much of these increased funds to improve the quality in our programs, as well as expand enrollment. We believe that given these recent increases, the low expected inflation rate for FY 1989, and the increasing number of programs which are receiving financial support from non-federal sources, most of our programs will be able to maintain their current level of enrollment and quality without another funding increase.

Question. Head Start is authorized at $1,332,000,000 for fiscal 1989; how would you utilize that level of funding?

Answer. An FY 1989 appropriation for Head Start of $1,332,000,000 would represent an increase of approximately $126 million over the FY 1988 funding level. If we were to receive an increase of this size we would follow our policy of the last few years to expand Head Start enrollment to improve program quality; and increase services to current enrollees. However, the offset is necessary to accommodate such an increase which are required by the Bipartisan Budget Agreement have not been identified.

## HEAD START - ELIGIBLE CHILDREN

Question. What percent of eligible children are currently served by Head Start?

Answer. Traditionally, Head Start has considered its eligible population as all 3, 4 and 5 year old children living in families with incomes below the poverty line. This figure is currently 2,500,000, of which Head Start serves a little less than 17 percent each year. However, it may be appropriate for Head Start to redefine its method of calculating its target population and what proportion of this population is being served. If one accepts that the availability of kindergarten in all fifty states means that Head Start, except in special circumstances, should no longer be serving five year olds, the target population is reduced by one-third, and is now 1,667,000, or all low income three and four year olds. However, this assumes that all such children should be served as both three and four year olds, or for two years. If, however, we assume that only a portion of Head Start children require two years of service, we would define our target population as all four year olds and some portion of the three year olds -- whatever portion should be served for two years.

Currently, Head Start programs serve approximately 20 percent of their enrollment for more than one year. If we accept this as a reasonable proportion, we would need to serve 167,000 children as three year olds who would then again be served as four year olds. This means that our target population would be something on the order of 1,000,000 children -- all four year olds and one fifth of the three year olds who would, of course, be served again as four year olds. Head Start, depending on the number of over-income and younger children enrolled in any given year, with current resources, serves between 40-45 percent of these children.

## ELIGIBLE PRE-SCHOOL POPULATION

Question. Has the growth in Head Start kept pace with the growth in the eligible pre-school population?

Answer. The growth in Head Start has largely kept pace with the growth in the eligible population. In FY 1980 Head Start served 18 percent of the eligible population each year; in FY 1987, approximately 17 percent of the eligible population were served each year.

## AGING SERVICES

Question. Your budget would "freeze" all programs authorized under the Older Americans Act at fiscal 1988 levels, totalling $701 million.

How can you justify not even maintaining current services, given the rapid expansion of the elderly population and the importance of these services to help keep older Americans out of institutional care?

Answer. The FY 1989 request for programs authorized under the Older Americans Act is consistent with the Bipartisan Budget Agreement. Slight increases in levels of services and meals are anticipated.

## FOSTER CARE ADMINISTRATIVE COSTS

Question. (BACKGROUND): Foster Care payments, including State administrative costs, are considered an entitlement; since 1983, appropriations have nearly doubled, from $572,669,000 to $1,074,907,000 requested for fiscal 1989. Your budget justification (page 159) indicates that Foster Care administrative costs have increased 500 percent over the last four years. Furthermore, administrative costs in 16 States have increased over 1,000 percent. Why have Foster Care administrative costs been increasing so dramatically, and do you expect this trend to continue?

Answer. States have increased their claims for Foster Care dramatically primarily by "Federalizing" the costs of staff activities, that is, they are mainly claiming more Federal funds for the same activities that they have been conducting. Under Title IV-E-Foster Care and Adoption Assistance, the activities that States are charging to the Federal Government are broader in scope than in most programs. States are amending their cost allocation plans to capture those costs.

Question: What have you done to control Foster Care administrative expenses, including audits of State costs?

Answer: First, the Office of Audit of the Office of the Inspector General has conducted 2 reviews of State claims in FY 1987. Second, OHDS has conducted 14 reviews of States administrative costs. Third, OHDS has conducted training of our regional staff and have broadened our interaction with the regional Division of Cost Allocation staff, to provide better review of proposed changes in plans to allocate administrative costs. OHDS and the Department are also reviewing sampling designs used in the cost allocation plans of some States in the central office. Finally, OHDS is working with staff in other parts of the Department to develop other means of appropriately limiting administrative costs.

## LIHEAP - ENERGY COSTS

While oil prices have dropped in recent years, the cost of natural gas, electricity, wood and coal appears to be going up. Overall, low-income home energy expenditures have stabilized between $8 and $9 billion since the early 1980's, according to Department of Energy data (see attached table).

Question. What is your projection over the next 10 years for fuel prices?

Answer. The most recent Department of Energy forecast indicates price stability until the mid 1990's. The energy market trend for the short term shows excess capacity with economic growth at about

2.2 % a year. After 1994, demand for fuel to meet an expanded economy will stimulate a moderate rise in energy prices.

The base case projection for residential fuels 1987-2000 is:

| | |
|---|---|
| Natural Gas | up 2.4% |
| Fuel Oil | up 2.8% |
| Electricity | down .2% |
| All Residential | up 1.4% |

If residential fuel prices increase only 1.4% per year, the percent of income paid for fuel should continue to decline.

Source: Annual Energy Outlook 1987, Energy Information Administration, U.S. Department of Energy, March 2, 1988.

Question. Do you expect there will continue to be a need for Federal assistance to help low-income people pay their fuel bills?

Answer. The Low Income Home Energy Assistance Program (LIHEAP) expires in September of 1990. The Administration will be reviewing and evaluating the program over the next two years.

Question. From February through September 1988, I understand that cash and medical assistance is being limited to refugees would are been in this country less than 24 months, down from the previous 31 months, due to cutbacks imposed by the fiscal year 1988 continuing resolution. This cut comes on top of the fiscal 1986 sequester, which reduced the eligibility period from 36 to 31 months. How much would have to be added to your fiscal 1989 budget request to restore cash and medical assistance to 31 months, based on the State Department's projection of 68,500 admissions?

Answer. An estimated $33.6 million in additional funding would be required in order to extend special Federal assistance for cash and medical benefits to 31 months of refugee eligibility.

HISTORICAL FUEL PRICES AND LOW INCOME HOME ENERGY EXPENDITURES
(All dollar values in current dollars)

| CALENDAR YEAR | NATURAL GAS ($/mmBtu) | FUEL OIL ($/mmBtu) | ELEC. ($/mmBtu) | WOOD & COAL (WEIGHTED) ($/mmBtu) | LOW INCOME HOME ENERGY EXPENDITURES | INDEX (1980=100) |
|---|---|---|---|---|---|---|
| 1970 | $0.96 | $1.32 | $6.37 | $1.46 | $1,967,692,672 | 29.26 |
| 1971 | $1.12 | $1.46 | $6.83 | $1.54 | $2,187,443,233 | 32.53 |
| 1972 | $1.19 | $1.47 | $7.10 | $1.61 | $2,277,697,940 | 33.87 |
| 1973 | $1.28 | $1.69 | $7.45 | $1.72 | $2,448,972,473 | 36.41 |
| 1974 | $1.42 | $2.61 | $8.08 | $1.87 | $3,060,858,798 | 45.51 |
| 1975 | $1.58 | $2.82 | $10.28 | $2.06 | $3,379,724,258 | 50.25 |
| 1976 | $1.84 | $2.94 | $11.00 | $2.19 | $3,787,303,871 | 56.32 |
| 1977 | $2.31 | $3.32 | $11.89 | $2.34 | $4,291,266,177 | 63.81 |
| 1978 | $2.52 | $3.51 | $12.88 | $2.61 | $4,608,421,684 | 68.52 |
| 1979 | $2.92 | $5.04 | $13.63 | $2.73 | $5,521,896,877 | 82.11 |
| 1980 | $3.50 | $6.58 | $15.96 | $2.97 | $6,725,287,544 | 100.00 |
| 1981 | $4.09 | $7.98 | $18.32 | $3.26 | $7,898,023,916 | 117.44 |
| 1982 | $4.92 | $7.85 | $20.09 | $3.47 | $8,671,306,041 | 128.94 |
| 1983 | $5.73 | $7.52 | $20.80 | $3.61 | $9,239,560,174 | 137.39 |
| 1984 | $5.75 | $7.56 | $21.84 | $3.74 | $9,395,467,855 | 139.70 |
| 1985 | $5.94 | $7.57 | $22.83 | $3.86 | $9,659,236,828 | 143.63 |
| 1986 | $5.66 | $6.06 | $22.86 | $3.96 | $8,973,823,795 | 133.43 |
| 1987 | $5.35 | $5.77 | $22.80 | $3.97 | $8,651,787,044 | 128.65 |
| 1988 | $5.17 | $5.95 | $22.45 | $4.21 | $8,562,872,000 | 127.32 |
| 1989 | $5.29 | 6.24 | 23.11 | $4.29 | $8,825,009,039 | 131.22 |

SOURCES: 1970-1984, DOE, Annual Energy Review, May, 1985 and May 1986, Table 11.
1985-1986, DOE, Short-Term Energy Outlook, April, 1987, Table 5.
1987-1989, DOE, Short-Term Energy Outlook, January, 1988, Table 5.

| | Low Income BTUs<br>Normal Winter | % | | |
|---|---|---|---|---|
| Nat. Gas | 720,551,036 | 0.568520 | | |
| Electricity(H) | 57,118,183 | 0.045086 | | |
| Fuel Oil | 242,884,829 | 0.191638 | | |
| LPG | 83,547,042 | 0.065919 | | |
| Kerosene | 19,812,756 | 0.015395 | | |
| Coal | 30,821,316 | 0.024318 | 0.348403 | |
| Wood | 57,843,169 | 0.046480 | 0.651596 | 3.97739510 |
| | (weighted 1987 price wood and coal) | | | |
| Electricity(C) | 56,335,302 | 0.043680 | | |
| Total | 1,287,413,732 | 1 | | |

**Source: 1987 Allocation Formula Data Base (MDB (A) based on RECS IV Consumption.**

Question. How much would be needed for 31 months of cash and medical assistance if additional workers of Armenians and Amerasians -- possibly as high as 30,000 -- are admitted to this country over and above the current State Department projection of 68,500 refugees?

Answer. It is estimated that an additional $83.9 million would permit ORR to extend for 31 months special Federal assistance for cash and medical benefits to 30,000 Armenian and Amerasian refugees over and above the current State Department projection of 68,500 arrivals, plus an estimated $5.3 million for the added State administration costs.

Question. I understand that you are projecting large unexpended balances in the targeted assistance program, so that fiscal 1988 appropriations may be sufficient to carry most States and counties throughout fiscal 1989, without any further appropriations. Why, then, is Dade County in my State being forced to severely curtail its targeted assistance programs? Rehabilitation staff working with ex-offenders, for instance, was just cut in half.

Answer. Dade and Jackson historically spend their entire allocation immediately, up front - whereas other counties are slower to spend and therefore have funds available longer.

Question. Why can't funds be re-allocated from areas with large unspent balances to help those projects facing unwarranted cuts?

Answer. Targeted assistance funds for the fiscal year beginning October 1, 1987, were appropriated on December 22, and Congress instructed that they be made available to States and counties as quickly as possible. Under this circumstance, time was not available to propose a new formula for the allocation of funds, to receive and analyze public comments on the proposal, and to issue a revised formula.

Question. Why couldn't unspent balances be used to help States facing severe cutbacks in their administrative funds?

Answer. Certain administrative and case management costs may be charged against targeted assistance funds, as follows:

--The direct and indirect administrative costs incurred for the overall management and operation of the State's refugee program, including its coordination, planning, policy and program development, oversight and monitoring, data collection and reporting, and travel:

If a State is a targeted assistance State, it may charge these costs against the five percent of the targeted assistance award which the statute permits to be used for State administrative costs.

-- Case management costs which, in previous years, States have claimed against the combined grant for cash and medical assistance and State administration:

The State may charge these case management costs against the five percent of the targeted assistance award permitted to be used for State administrative costs. If a county is a targeted assistance county, the county may charge these case management costs against its targeted assistance award.

Question. Provide for the record, by county and State, your estimate of targeted assistance funds that will still not be spent by December 31, 1988.

Answer. This information will be available after all FY 1988 targeted assistance applications have been received and analyzed. The final due date for applications was May 13, and we will be pleased to provide the information as soon as possible thereafter.

Question. What percentage of child support payments are currently being collected, and what progress is being made to improve collections?

Answer. In FY 1987, State child support programs collected 49.0 percent of the support owed on IV-D cases during the year. This was up from 45.8 percent in FY 1986, the first year in which data was reported. With respect to support owed in prior years but not paid, State child support programs collected 8.6 percent of past support owed in IV-D cases in FY 1986 and 7.7 percent in FY 1987. Overall child support collections were up by over 20 percent between FY 1986 and FY 1987, as a result of OCSE initiatives to implement the 1984 Amendments more effectively and to improve coordination of the child support enforcement and AFDC programs.

Question. Is it justified that the States continue to collect more than they have to pay for this program, while the Federal partner continues to receive far less than it pays?

Answer. The Federal government pays an average of 90% of State administrative costs. States pay 10 percent of costs, and keep 45% of savings; we expect this disparity to continue to increase. The Child Support Enforcement Amendments of 1984, set Federal reimbursement of State costs for administering the program at 68 percent and incentives paid to the States at 6 to 10 percent of collections.

## STATUS OF ADMINISTRATON ON AGING

Last fall, the President signed legislation re-authorizing the Older Americans Act, including a provision requiring that the Commissioner on Aging report directly to the Secretary. In

January, you issued a memorandum indicating the Commissioner on Aging shall report directly to you, but did not elevate the organizational status of the Administration on Aging.

Question. How can the Administration on Aging remain a component of the Office of Human Development Services and still report directly to the Secretary?

Answer. On January 28, 1988, the Secretary of Health and Human Services issued a memorandum to all STAFFDIV and OPDIV Heads declaring that the Commissioner of Aging reports directly to him. In that same memo, the Assistant Secretary for Management and Budget was charged with examining and making recommendations on organizational and support matters concerning the Administration on Aging raised by the recent amendments. The ASMB has set October 1, 1988 as a completion date for his study. In the interim, AoA will continue to receive logistic and administrative support through the Office of Human Development Services.

Question. Do you intend to have the Commissioner on Aging directly involve in all key policy decisions regarding matters under the jurisdiction of the Administration on Aging, including its proper organizational status?

Answer. As indicated in the Secretary's January 28, 1988 memorandum, the Commissioner on Aging will report directly to the Secretary on matters involving the formulation and interpretation of policy, including those functions which are placed in the Commissioner by the Older Americans Act. However, the authorities with respect to personnel, budget, reorganization and related administrative and management matters are all vested in the Secretary who has directed the Assistant Secretary for Management and Budget to examine and make recommendations on organizational and support matters concerning AoA. The ASMB plans to complete this study of AoA by October 1, 1988. AoA will be consulted throughout the study.

Question. Has the Commissioner on Aging been directly involved in developing regulations for implementing recently enacted amendments to the Older Americans Act?

Answer. Yes, the Commissioner on Aging was directly involved in the development of the regulations for implementing recently enacted amendments to the Older Americans Act.

Question. Will the Commissioner on Aging no longer have to clear draft regulations and policy matters through the Assistant Secretary for Human Development?

Answer. The Commissioner on Aging now reports directly to the Secretary on all matters involving the formulation and interpretation of policy, including those functions which are placed in the Commissioner by the Older Americans Act. The development and issuance of draft regulations fall into this category.

## WELFARE REFORM - WORK INCENTIVE PROGRAM

Question. The President's budget proposes $505 million for a new job training program, as part of welfare reform legislation. At the same time, you propose terminating the existing $100 million Work Incentive Program, which helps welfare clients obtain jobs. Doesn't it make sense to keep the Work Incentive Program alive until its replacement is created and funded, so the existing staff expertise can be phased into the new program?

Background: The House-passed Welfare Reform legislation keeps the Work Incentive Program going for two more years, for a gradual transition to the large replacement program; the bill being considered in the Senate Finance Committee would convert WIN to an entitlement program.

Answer. The AFDC Employment and Training Reorganization Act, which we support, provides a full year's funding for the replacement work program, beginning in FY 1989. Since WIN is funded through FY 1988, there need not be any interruption in funding to the States for operation of AFDC work program activities.

Also, we believe that States will have little difficulty phasing in existing staff and making the transition to the new program. Most State welfare agencies already have substantial involvement in providing employment-related services (through the WIN Demonstration, Community Work Experience, Employment Search and Grant Diversion programs) and will able to build upon these existing programs.

Question. What is there about your proposed new program that will make it better than the existing one?

Answer. There are important differences between WIN and the AFDC Employment and Training Reorganization Act of 1987 (S. 155), which we support ,which would make the new program substantially more effective than the current set of activities. These include:

1) changes in the exemption rules to enable early intervention with young welfare parents and other potential long-term recipients;

2) participation standards to ensure that a significant share of adult and teen recipients receive employment related services;

3) coordinated administration and responsible funding to ease program administration and to improve program efficiency;

4) special focus on school completion for teen dependents and teen parents in order to break the cycle of long-term dependency;

5) emphasis on activities which have proven effective in reducing dependency.

## DEFICIENCIES IN NIH PROCUREMENT

Question. I understand the House Appropriations Subcommittee, in marking up the fiscal 1988 supplemental on Wednesday of this week, has recommended a $5 million rescission in NIH funds. This was in response to five consecutive Inspector General and other reports indicating serious deficiencies in the NIH procurement program. The Inspector General has indicated that "26 million in precious research funds are being lost each year due to inefficiency and mismanagement."

The Inspector General report indicated that intervention by the Secretary was necessary to correct this long standing problem.

Please tell the Committee your plans to insure these problems are corrected.

Answer. While there has been considerable disagreement as to the magnitude of the problem, I want to assure the committee that NIH recognizes there are deficiencies in its purchasing practices and that corrective action has already begun. Some initial steps taken by NIH include,

- o realigning the procurement function under the Office of Administration;
- o establishing a senior advisory group for coordination of corrective actions and procurement policies; and
- o designating a single official responsible for procurement oversight.

Also, the Director, NIH has issued a memorandum emphasizing the need for senior management staff to communicate and reinforce at all organizational levels that cost economy and regulatory compliance are important purchasing system objectives.

In addition, NIH is currently developing a comprehensive corrective action plan. Major features will include,

- o Making senior procurement and supply officials accountable for achieving cost economies and regulatory compliance in their respective areas:
- o Making informed buying decisions and negotiating appropriate discount terms with vendors;
- o Reexamining the entire decentralized procurement structure to increase productivity, reduce the number of personnel who can place orders and better train and equip those that do; and
- o Strengthening the central monitoring capability over all decentralized purchasing activities.

I believe such actions are necessary and appropriate and will improve NIH's purchasing practices significantly.

## FRAUDULENT SCIENCE AT NIH

Question. A recent Jack Anderson article in the Washington Post claims that the potential for fraud in NIH-sponsored biomedical research is high. Representative Dingell has stated that NIH oversight over potentially fraudulent science is "hopelessly inadequate."

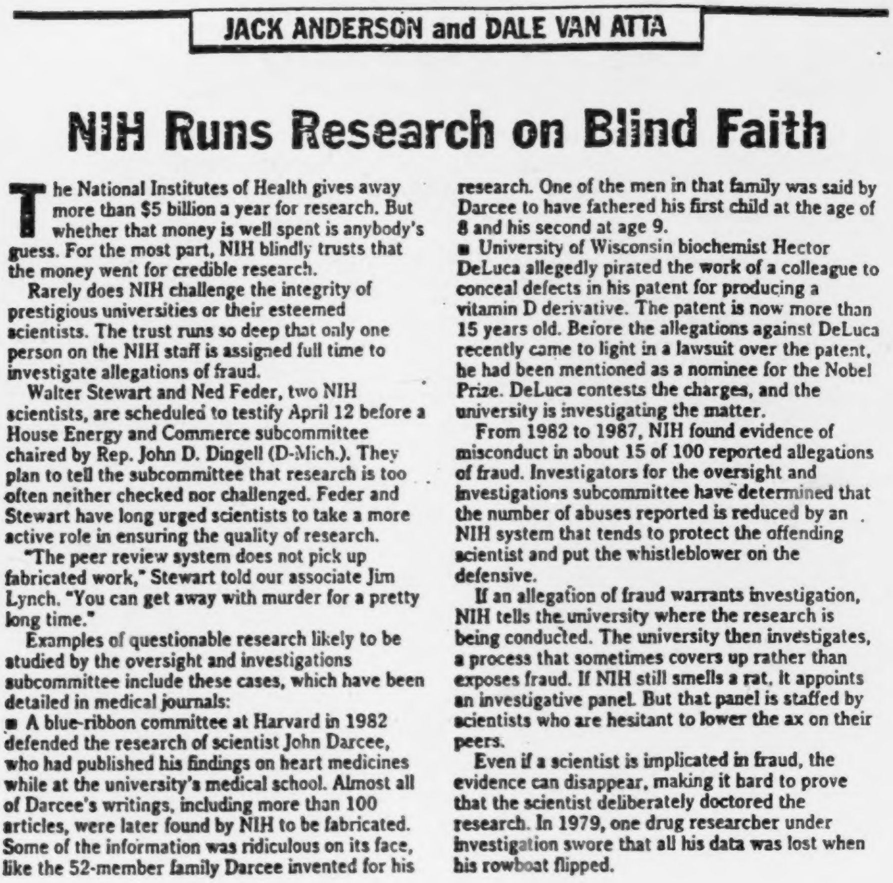
We learned in hearings with NIH that they have only two professionals to investigate research fraud, and the peer review system is not designed to pick up fabricated work.

What more needs to be done to protect against potentially fraudulent science? Nothing could faster erode the support that NIH enjoys than several cases of fraudulent science.

Answer. We agree that even a few cases of research fraud are cause for concern. The funding agencies, research institutions, and individual scientists all have a responsibility to promote the highest standards in research, encourage the reporting of deceptive or questionable practices, and deal forthrightly with those who abuse the trust of their colleagues and the public.

We have taken and are planning several steps to improve our capacity to deal with fraud and misconduct in research. We have added staff to the NIH office responsible for this activity and have funded or participated in conferences and workshops directed at a wide range of issues related to this topic. Also underway are plans to provide the research institutions with more explicit guidance as to their responsibilities, efforts to educate the research community, and selective monitoring of the institutions' procedures.

[From the Washington Post, Apr. 11, 1988]



**JACK ANDERSON and DALE VAN ATTA**

# NIH Runs Research on Blind Faith

The National Institutes of Health gives away more than $5 billion a year for research. But whether that money is well spent is anybody's guess. For the most part, NIH blindly trusts that the money went for credible research.

Rarely does NIH challenge the integrity of prestigious universities or their esteemed scientists. The trust runs so deep that only one person on the NIH staff is assigned full time to investigate allegations of fraud.

Walter Stewart and Ned Feder, two NIH scientists, are scheduled to testify April 12 before a House Energy and Commerce subcommittee chaired by Rep. John D. Dingell (D-Mich.). They plan to tell the subcommittee that research is too often neither checked nor challenged. Feder and Stewart have long urged scientists to take a more active role in ensuring the quality of research.

"The peer review system does not pick up fabricated work," Stewart told our associate Jim Lynch. "You can get away with murder for a pretty long time."

Examples of questionable research likely to be studied by the oversight and investigations subcommittee include these cases, which have been detailed in medical journals:

- A blue-ribbon committee at Harvard in 1982 defended the research of scientist John Darcee, who had published his findings on heart medicines while at the university's medical school. Almost all of Darcee's writings, including more than 100 articles, were later found by NIH to be fabricated. Some of the information was ridiculous on its face, like the 52-member family Darcee invented for his research. One of the men in that family was said by Darcee to have fathered his first child at the age of 8 and his second at age 9.
- University of Wisconsin biochemist Hector DeLuca allegedly pirated the work of a colleague to conceal defects in his patent for producing a vitamin D derivative. The patent is now more than 15 years old. Before the allegations against DeLuca recently came to light in a lawsuit over the patent, he had been mentioned as a nominee for the Nobel Prize. DeLuca contests the charges, and the university is investigating the matter.

From 1982 to 1987, NIH found evidence of misconduct in about 15 of 100 reported allegations of fraud. Investigators for the oversight and investigations subcommittee have determined that the number of abuses reported is reduced by an NIH system that tends to protect the offending scientist and put the whistleblower on the defensive.

If an allegation of fraud warrants investigation, NIH tells the university where the research is being conducted. The university then investigates, a process that sometimes covers up rather than exposes fraud. If NIH still smells a rat, it appoints an investigative panel. But that panel is staffed by scientists who are hesitant to lower the ax on their peers.

Even if a scientist is implicated in fraud, the evidence can disappear, making it hard to prove that the scientist deliberately doctored the research. In 1979, one drug researcher under investigation swore that all his data was lost when his rowboat flipped.

CATASTROPHIC HEALTH - BENEFICIARY EDUCATION

Mr. Secretary, the budget request includes $112 million to implement the catastrophic health insurance program, when it becomes law. This request includes funding for beneficiary education.

As you may know, I included a provision on the catastrophic legislation to train volunteers for benefits counseling and assistance. This program is modeled on the Tax Counseling for the Elderly program, which is administered by the Internal Revenue Service (IRS).

I'm interested in your planned efforts to educate Medicare beneficiaries about the new catastrophic health benefits.

Question. Do you plan to use trained volunteers to counsel beneficiaries?

Answer. At this time, we do not plan to use volunteers working directly with the government to educate Medicare beneficiaries. We are working with a number of interest groups, such as the AARP, and their volunteers will help to educate beneficiaries.

Question. Briefly, how do you plan to educate beneficiaries?

Answer. Funds have been built into the catastrophic contingency funds to prepare public service announcements and publish new Medicare Handbooks, pamphlets and press releases to educate beneficiaries and the public.

We also plan to produce a video tape which will be available for senior citizen centers to use and we will contract for a 800-hotline to answer beneficiaries' specific questions.

Question. Mr. Secretary, do you have any thoughts on an incremental approach to a comprehensive long-term care program?

Answer. As I have stated on a number of occasions, I prefer a private sector solution to the issue of long-term care.

I am not in favor of a new long-term care entitlement program. Specifically, we need to continue to explore such options as private sector insurance or individual savings accounts possibly coupled with tax incentives.

## PEDIATRIC AIDS

Question. Mr. Secretary, both you and I share a grave concern for the growing incidence of infants and children with AIDS. Researchers are projecting 10,000 to 20,000 infants and children with AIDS by 1991.

As you know, we provided funding in our bill last year for research into how a mother transmits AIDS to her infant. We also provided funding for health services projects to demonstrate ways to provide care for these children in setting other than hospitals.

I understand that you have organized a pediatric AIDS task force that will report recommendations to you in September. Can you share with us any preliminary findings of your task force? Should we be devoting more resources to tackling this problem?

Answer. We estimate the Department will spend about $76 million in 1989 directly on pediatric AIDS activities. This is an increase of $18 million over 1988 and $56 million over 1987, an increase of 280% in just 2 years.

On February 26th, the Department announced the creation of an initiative to focus attention on pediatric AIDS. The Assistant Secretary for Health will lead the cross-agency initiative to ensure that we make use of not only the best medical response, but also the best social service programs on behalf of these children and their families.

A Pediatric AIDS Task Force has been established, headed by Dr. Antonia Novello, Deputy Director of the National Institute of Child Health and Human Development. The Task Force should issue findings later this year. The initiative has several purposes:

- To provide a focus for the issue in the Department.
- To review Departmental policy to eliminate unnecessary barriers to timely utilization of program benefits.
- To develop a coordinated research and demonstration agenda.
- To provide technical assistance to local communities, institutions and agencies.
- To suggest prevention activities that can be undertaken to discourage infected women from having children.

The Department is currently addressing the issue of pediatric AIDS in numbers of ways:

- A national conference was held in April 1987, leading to a report by the Surgeon General on pediatric AIDS issues.
- Research: NIH, CDC, and ADAMHA will spend $64 million in 1989 on research into the efficacy of treatment protocols in children and women of childbearing age, and the natural history of the disease in these populations. An additional benefit of these studies is that the funds help support a range of medical and social services staff at hospitals and research medical centers who work with infected children and their families.
- "Boarder Babies" Welfare Services: The Office of Human Development Services (OHDS) expects to spend approximately $1.2 million for demonstration projects to establish innovative child welfare services for infants and young children who have tested positive for AIDS and whose parents are unable to care for them, often abandoning them in hospitals.
- Services/Prevention: HRSA and CDC will spend $11 million in 1989 on pediatric AIDS health care demonstrations and on projects to prevent perinatal transmission of AIDS from HIV-infected mothers to their newborn children.
- IV Drug Abuse: While not specifically directed to pediatric AIDS, ADAMHA (NIDA) will spend $54 million in 1989 on community-based outreach and prevention projects targeted to inner city youth, minorities and drug abusers which will indirectly impact pediatric AIDS.
- About 70% of all pediatric AIDS cases due to perinatal

transmission occur in infants born to IV drug abusers or women who are their sexual partners. About 50% of all infants born to HIV-infected mothers contract the infection, either in-vitro or during delivery.

The following table provides a summary of our pediatric AIDS spending:

HHS - PEDIATRIC AIDS EXPENDITURES (Dollars in 000s)

|  |  |  | 1989 |  |
|---|---|---|---|---|
|  | 1987 | 1988 | Pres. Budget | Inc. |
| PHS: |  |  |  |  |
| HRSA: |  |  |  |  |
| Pediatric AIDS Health Care Demonstrations..... | --- | $4,787 | $5,000 | $213 |
| CDC: |  |  |  |  |
| Pediatric AIDS Surveillance............ | $300 | 1,000 | 1,000 | --- |
| Perinatal Transmission Studies................. | 800 | 2,000 | 2,000 | --- |
| Perinatal AIDS Prevention Demonstrations.......... | 1,600 | 6,300 | 6,400 | 100 |
| Natural History Studies... | 1,200 | 1,300 | 1,400 | 100 |
| Neonatal Seroprevalence Studies................. | --- | 8,400 | 8,400 | --- |
| Subtotal, CDC......... | $3,900 | $19,000 | $19,200 | $200 |
| NIH: |  |  |  |  |
| NCI...................... | 2,402 | 2,758 | 3,021 | 263 |
| NHLBI.................... | --- | --- | 1,500 | 1,500 |
| NINCDS................... | 438 | 1,658 | 1,960 | 302 |
| NIAID.................... | 5,494 | 13,910 | 20,247 | 6,337 |
| NICHD.................... | 2,613 | 10,082 | 14,460 | 4,378 |
| DRR...................... | 342 | 1,051 | 4,142 | 3,091 |
| Subtotal, NIH........... | 11,289 | 29,459 | 45,330 | 15,871 |
| ADAMHA: |  |  |  |  |
| NIMH..................... | 3,500 | 3,650 | 4,550 | 900 |
| NIDA..................... | 860 | 860 | 860 | --- |
| Subtotal, ADAMHA........ | 4,360 | 4,510 | 5,410 | 900 |
| Total, PHS................ | 19,549 | 57,756 | 74,940 | 17,184 |
| OHDS: |  |  |  |  |
| Child Welfare Services Demonstrations........... | --- | 1,200 | 1,200 | --- |
| TOTAL, HHS Pediatric AIDS... | $19,549 | $58,956 | $76,140 | $17,184 |

## COMMISSION ON NURSING SHORTAGE

Question. Mr. Secretary, this past January, you created a Commission on Nursing to study the recruitment and retention of registered nurses in the United States. I understand that, although the final report is due in December, there will be an interim report issued this May (next month).

Can you share with us any preliminary recommendations the Commission has formulated to address the nursing shortage?

Answer. The Commission on Nursing is in the process of completing work on their interim report, targeted for the end of May as you are aware. This report will asses the scope and nature of the problem through a series of findings about the supply and demand for nurses. The Commission must complete this activity before considering recommendations appropriate to the problem. The Commissioners will begin deliberating possible recommendations at their May meeting and will continue this endeavor for several meetings. At such time that the Commission has preliminary recommendations available, we would be pleased to discuss sharing them with you.

Question. As you know, we provided $1 million in the FY 1987 supplemental to the Department to study the nursing shortage. Part of that supplemental supported a national workshop on the nursing shortage this past February.

Will the Commission use any of the recommendations coming out of that national workshop?

Answer. Two cooperative conferences which addressed the nurse shortage were conducted in February by the Department. The National Center for Nursing Research sponsored the State-of-the-Science Invitational Conference: Nursing Resources and the Delivery of Patient Care. This meeting was immediately followed by the National Invitational Workshop on the Nursing Shortage: Strategies for Nursing Practice and Education under the aegis of the Division of Nursing, Health Resources and Services Administration. The Chairperson of the Commission, Dr. Carolyne K. Davis, and her staff participated in both conferences, and representatives of the sponsoring components summarized their respective meetings for the Commissioners at the March meeting. Consensus is that these workshops were very valuable and informative, and that the recommendations evolving from them will be utilized by the Commission, especially toward the development of models for the recruitment and retention of nurses in the practice of nursing.

## INADEQUATE CHILD PROTECTION SUPERVISION

Question. According to press reports, about 35 to 55 percent of all child fatalities attributed to abuse or neglect involve children already reported to a child protection agency. Are these figures accurate?

Answer. There are no national studies of fatalities attributed to child abuse and neglect which document the percent of children involved who were already reported to a child protection agency. Local studies have been done which suggest that between 25-50 percent of the cases of fatal abuse and neglect are from families previously or currently known to the child protection agency or another agency in the community. Basically we do not know whether these figures are accurate or not.

Question. Can better management in child protection agencies help solve this problem -- or are these cases of child abuse unpreventable?

Answer. At the present time very little is known which would help an agency focus on the high risk populations. Although several research studies have been completed on child fatalities (mostly retrospective analyses in local communities of child deaths due to maltreatment), very little is known about what causes these deaths or how to prevent them. Other than the fact that infants under the age of one are particularly vulnerable to fatal maltreatment, there are no definitive profiles of persons who will severely batter or kill children or of children who are at risk.

The total number of child fatalities due to maltreatment is too small (hovering at about 1,100 cases per year, according to the national incidence studies of 1980 and 1986) to develop valid predictions of which individuals might fatally injure children. However, in FY 1988 HDS is soliciting proposals to look at whether there are any clear causes or indicators which will help protective service workers to distinguish those situations where children are at risk of fatal injury.

The two approaches most widely accepted by the field for reducing child maltreatment fatalities are:

- Establishing child death investigations teams in a community, involving the medical examiner, law enforcement, child protection, health services and prosecutor's offices. The purpose of such teams is to review all child deaths reported to the coroner's office, and to have a procedure for the medical examiner and others involved in the team to investigate the causes of death more systematically.

- The establishment of effective community-wide prevention programs targeting high risk populations, so as to increase the awareness of people of the possibility of fatal maltreatment and the need to report even a single abusive incident. A number of strategies have been suggested for these prevention programs, including home health visitors for first time pregnancies, the training of parents in nurturing skills, and the education of children in nonviolent handling of infants.

In FY 1988 HDS is soliciting applications for demonstration programs to reduce child fatalities through such community wide models.

## DRUG ABUSE TREATMENT FUNDING

Question. Dr. Bowen, many inside and outside Congress are calling for an expansion in drug abuse treatment services, especially in light of the threat of transmitting the AIDS virus through IV drug abuse. The Federal Government makes a fairly modest contribution to the cost of drug treatment services--about 18 percent of the total spent.

Can the States be expected to bear the burden of the cost of expanded drug treatment? Hasn't the time come for the Federal Government to shoulder more of the load?

Answer. The Department is currently reviewing plans that include the possibility of expansion of Federal involvement and how this might be accomplished. One plan currently under review would involve a joint Federal/State effort to expand treatment over a five year period.

Question. Should the Federal Government provide funding for the renovation or construction of the additional treatment facilities that will be required?

Answer. Any significant expansion of the nation's drug abuse treatment capacity would require new treatment clinics. Such an effort might require Federal support, however, we also believe that the States should share part of the cost.

## Two-Year Appropriations

Question. Dr. Bowen, we were surprised that your Health and Human Serviced budget requested two-year appropriations, especially since none of the other agencies funded by our bill followed suit.

Why did you stand alone and propose two-year funding when it wasn't a government-wide policy?

Answer: In the January 25 State of the Union Address, the President stated unequivocally that the budget process has broken down and needs a drastic overhaul.

The President recalled that over the last seven years, only ten of the scheduled 91 appropriations bills were provided to him on time. None made it for 1988. In fact, the Government operated for 82 days in 1988 under four separate Continuing Resolutions before reaching the final Bipartisan Budget Agreement.

A key element of the President's 1989 Budget is to recommend budget process reform, of which biennial budgeting is a major reform item.

As you will recall, Gramm, Rudman, Hollings II of September 1987 included a sense-of-the-Congress provision urging Congress to experiment with two-year appropriations. The Department of Health and Human Services was chosen by the Administration to cooperate with this Subcommittee for that purpose.

Question. How were you able to make estimates for fiscal year 1990 -- the guidance from the deficit reduction agreement only applied to 1988 and 1989?

Answer. The 1990 budget request was based on economic assumptions included in the President's Budget. Each Operating Division used these economic assumptions to project their estimates for current law estimates. In addition, legislative proposals were included in estimates for 1990 through 1993.

Detailed inflation factors used to calculate out-year projections by Operating Division are as follows:

Public Health Service:

Grants - State and local purchases deflator (3.9%)

Direct medical service - Medical CPIU (5.8%)

Administrative costs - Non-defense/non-pay purchase deflator (3.6%)

Health Care Financing Administration:

Research and Medicare - one half of Medical CPIU (2.9%)

State Certification - one half State and local purchases deflator (1.95%)

Administrative costs - one half of non-defense/non-pay purchase deflator (1.8%)

PROs - no deflator

Social Security Administration:

Administrative costs - Non-defense/non-pay purchase deflator (3.6%)

Family Support Administration:

All programs - State and local purchases deflator (3.9%)

Office of Human Development Services:

All programs - 2.0%

Office of the Secretary:

All programs - non-defense/non-pay purchase deflator (3.6%)

## SOCIAL SERVICES BLOCK GRANT

Question. Why didn't you request a $50 million supplemental to fully fund this entitlement program?

Answer. As worked out by the House and the Senate, the FY 1988 continuing resolution includes $2.7 billion for the Social Services Block Grant (SSBG). While we recognize that the reconciliation bill included a one-time $50 million authorization increase for the SSBG, the President has agreed to the Congressional level of $2.7 billion. As part of the Bipartisan Budget Agreement, the Administration agreed to seek supplemental appropriations except in the case of a dire emergency.

Question. Couldn't these added funds be effectively used to help alleviate the backlog of low-income people seeking child care assistance?

Answer. Under the Social Services Block Grant (SSBG), each State has the flexibility to determine what services are provided, who is eligible to receive services, and how funds are distributed among the various services offered within the State. Therefore, if additional SSBG funds were made available, it would be up to each State to determine the funding priorities for the various social services offered by the State.

Question. Dr. Bowen, your Department has put out material suggesting that you are proposing a 7 percent increase in funding for the homeless over the 1988 level. But those totals include funds from regular, on-going programs like Medicaid, which serve the homeless as part of their eligible client pool. When you look at funding specifically targeted to the homeless by the Stuart B. McKinney Act, the 1989 total actually drops by almost 14 percent. Given these numbers, don't we have to question the sincerity of the Administration's rhetoric about compassion for the homeless?

BACKGROUND

| | HHS Version | | Senate Version McKinney Act Programs | |
|---|---|---|---|---|
| | 1988 | 1989 | 1988 | 1989 |
| ADAMHA | 18 | 37 | 11 | 23 |
| HRS | 14 | 15 | 14 | 15 |
| FSA | 19 | -- | 19 | -- |
| HDS | 26 | 26 | -- | -- |
| Medicaid | 10 | 15 | -- | -- |
| TOTAL | 87 | 93 | 44 | 38 |
| | +7% | | -14% | |

Answer. We have been very careful to comprehensively score for budget presentation HHS programs which are directed specifically to the homeless. As you state, the Department has many programs which could be considered homeless prevention activities and programs which serve the homeless as part of a larger population pool. Since these programs are not targeted specifically to the homeless, data needed to quantify these efforts is not readily available and no effort has been made by the Administration to score the homeless portion of these program funds.

We believe it is somewhat misleading to focus solely on programs authorized by the Stewart B. McKinney Homeless Assistance Act when there are other Departmental programs which target the homeless. For this reason, our summary of homeless program funds reflects efforts beyond the scope of this Act. In all, the Administration proposes funding of $94 million specifically for the homeless in 1989, about a 7% increase in budget authority over 1988. Of this amount, $39 million will fund continuation of Stuart B. McKinney Homeless Assistance Act activities and $55 million will fund other HHS programs which exclusively serve the homeless.

I would like to clarify that the $15 million identified in 1989 Medicaid funds is not part of the regular, on-going Medicaid program. These funds will be used to provide clinical services in non-traditional settings exclusively to the homeless as authorized by the Omnibus Budget Reconciliation Act of 1987 (P.L. 100-203). This is an increase of $5 million over 1988 funding for these activities. In addition, we have proposed doubling our efforts over 1988 for ADAMHA Community Support Program Homeless Demonstrations in the 1989 President's Budget -- from $7 million to $14 million. We have also proposed funding the Runaway and Homeless Youth program at the 1988 level of $26 million. I believe the 1989 President's Budget reflects sincere support of public health and social service programs for the homeless.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HOMELESS FUNDING

(Budget Authority in Thousands)

| | FY 1987 | FY 1988 | FY 1989 |
|---|---|---|---|
| ADAMHA: | | | |
| o Community Support Program Homeless Demonstrations.............. | 1,144 | 6,643 | 13,821 |
| o Homeless Demonstrations*............. | 9,300 | 0 | 4,650 |
| o NIAAA Community Demonstrations*....... | 9,200 | 0 | 4,600 |
| o Services Grants To States/Homeless Mentally Ill*....................... | 32,200 | 11,489 | 14,300 |
| Subtotal, ADAMHA................ | 51,844 | 18,132 | 37,371 |
| HRSA: | | | |
| o Primary Care Grants*............... | 46,000 | 14,361 | 15,000 |
| FSA: | | | |
| o Community Services for the Homeless*....................... | 36,600 | 19,148 | 0 |
| o Federal Task Force on the Homeless*... | 200 | 0 | 0 |
| Subtotal, FSA................... | 36,800 | 19,148 | 0 |
| HDS: | | | |
| o Runaway & Homeless Youth............. | 23,250 | 26,089 | 26,089 |

| | | | |
|---|---|---|---|
| HCFA: | | | |
| o Medicaid Clinical Services | 0 | 10,000 | 15,000 |
| Total | 157,894 ** | 87,730 ** | 93,460 ** |

* Stewart B. McKinney Homeless Assistence Act (P.L. 100-77), for FY87 and FY88. Authorizations expire on 9/30/88.

** Excludes an additional $12 million for Mental Health Services for those individuals who are at risk of becoming homeless and other prevention activities which cannot be quantified such as SSI; AFDC; SSDI; Social Services Block Grants; Community Services Block Grants; Community Health Centers and Alcohol, Drug Abuse and Mental Health Block Grants.

## REFUGEES - CUTS IN STATE ADMINISTRATIVE COSTS

Question. I joined several other Senators in sending Secretary Bowen a letter on March 4, 1988, seeking relief for States which are being forced to virtually shut down their refugee offices due to cutbacks which are being compressed into the remaining few months of fiscal year 1988. What is your current assessment of the problem facing State Refugee offices, and what assistance can you offer?

Answer. States have indicated to us that they were facing problems because of the lower amount of funds appropriated for State administration than expected and because notification was received only after the fiscal year was well underway. We have tried to be as helpful as possible by providing available funds and the maximum flexibility possible. For example, States can charge certain administrative and case management costs against targeted assistance funds.

Question. Would you consider allowing the States flexibility to charge administrative costs as long as the States operate within the overall program allocation limits?

Answer. We concur with the proposal to allow States the maximum flexibility in charging administrative costs within overall program allocation limits and have advised the States as follows on this matter: "The following clarifications are intended to provide States with the maximum flexibility permissible within the current appropriation structure and the funds available for the refugee program. States may charge the following types of administrative costs against refugee program grants other than the grant for State administration, as specified below:

-- The direct and indirect administrative costs incurred for the overall management and operation of the State's refugee programs, including its coordination, planning, policy and program development, oversight and monitoring, data collection and reporting, and travel:

"The State may charge these costs against its refugee program social service grant and/or, if the State is a targeted assistance State, against the five percent of the targeted assistance award permitted to be used for State administrative costs.

-- Case management costs which, in previous years, States have claimed against the combined grant for cash and medical assistance and State administration:

"The State may charge these case management costs against its refugee program social service grant and/or, if the State is a targeted assistance award permitted to be used for State administrative costs. If a county is a targeted assistance county, the county may charge these case management costs against its targeted assistance award.

Question. Have you explored the possibility for reprogramming any unspent or unobligated funds in other components of the refugee program?

Answer. We decided not to seek a reprogramming of funds from other refugee program activities because of the need for the funds appropriated for those activities -- cash and medical assistance, social services, targeted assistance, preventive health, and the voluntary agency matching-grant program.

## HOMELESS FAMILIES

Question. The Family Support Administration is supposed to be the lead Federal agency to assist and strengthen hard-pressed families in this country. Do you know what percent of the homeless in America are members of families with children?

Answer. A national study conducted by the Department of Housing and Urban Development in 1984 found that approximately 66% of the homeless who use shelters are single men, 13 percent are single women, and 21 percent are members of family groups.

Question. What have you been able to accomplish to assist homeless families?

Answer. States and Indian tribes funded under the OCS homeless grant program are required to submit an annual report on their expenditures of FY 1987 funds by November 30, 1988. Most of the funds were disbursed to the States within the last 5 months, and annual reports are not yet available. Since no other reports are required of the grantees, we have limited knowledge of the types of services provided at this time. However, the States were required to apply for the money and to advise OCS of the types of activities they intended to fund. In addition, States must award 90 percent of the funds to organizations that were providing services to the homeless as of January 1, 1987, although those organizations could expand or amend the types of services offered.

Based on the FY 1987 applications and our knowledge of previous community action agency activities, we believe the following types of homeless assistance are being offered to families as well as individuals:

- emergency and temporary shelter
- food provided through pantries
- medical and/or transportation assistance
- counselling on drug abuse, domestic violence and runaways
- referral to other agencies, groups and/or services
- clothing, blankets and emergency assistance
- housing assistance
- employment assistance and hiring incentives to private sector organizations

- outreach assessment and counselling
- fund solicitation from companies and corporations
- promotion of fund raising efforts to help build or buy
- buildings for conversion into shelters
- day care

Question. How are funds earmarked for the homeless under the Community Services Block Grant being utilized?

Answer. There are no funds earmarked for the homeless under the Community Services Block Grant Program (CSBG). Because CSBG is a block grant, the funds may be used for a wide variety of programs at the discretion of States and localities. A new program entitled the Emergency Community Services Homeless Grant Program (EHP) was established in 1987 by the Stewart B. McKinney Homeless Assistance Act (Public Law 100-77) to be operated by OCS to help homeless persons, including families. Although the EHP program is similar in many ways to the CSBG program, including the fact that it is administered by OCS, it is legally and operationally separate.

Question. Do you see the problem of homelessness as getting worse in America?

Answer. Clearly, the homeless are much more visible today than they were a few years ago, and they are more willing to ask for assistance. Many State, local and private sector groups have reported increases in requests for help from homeless individuals and families. This may be the result, at least in part, of increased publicity about homeless people, and a resulting reduction in the stigma attached to being homeless. State and local governments working together with the private sector and aided by the Federal government can keep this problem from becoming worse.

Question. What specific recommendations do you have to better meet the problem of homelessness and homeless families in particular?

Answer. Because the causes of homelessness are so wide-ranging, it is important to understand that there is no single solution, and that each group must be dealt with on its own merits. In addition, the main causes of homelessness, and thus its solutions, often vary between small and large cities and rural areas, and from one region of the country to another. What works in one place may not work in another.

For this reason, new Federal programs are not the answer. State and local governments must take the lead with private sector groups to develop solutions to homelessness that deal with the root causes in its own areas. Consequently, we do not have a recommendation that we feel we can promote in all areas. In general, however, we believe it is necessary to deal with the underlying causes of homelessness in each area, rather than simply focusing on emergency assistance. Although emergency assistance is sometimes necessary for immediate shelter, it does nothing to eliminate or reduce homelessness in the long run.

## OVERALL IMPACT OF ANTI-POVERTY PROGRAMS

Question. For several years, this Administration has tried to abolish targeted assistance for refugees, the Work Incentive (WIN) Program to train welfare mothers, and phase out anti-poverty programs under the Community Services Block Grant. Despite your desire to see these programs eliminated, have you been able to administer them effectively?

Answer. We consider the refugee targeted assistance program to be working generally well, after experiencing some problems in various locations in earlier years. However, it must be remembered that the targeted assistance program was established to address the special impacts that resulted from large numbers of refugees and Cuban/Haitian entrants who arrived in fiscal years 1980-1982.

The Department of Labor has had primary responsibility for the administration of the regular Work Incentive (WIN) program and would be in a better position to address questions about its administration. However, the basic conclusion of the Administration has been that the WIN program was not effective in reducing welfare dependency. HHS has been responsible for administration of the WIN Demonstration program, which has been operated as an alternative to the regular WIN program in twenty-nine States. Our basic philosophy in administering this program, which was authorized for a limited number of years, was to allow States broad flexibility in designing their programs and to minimize burdensome administrative requirements for the States. Over the past seven years, the WIN Demonstration option has become increasingly popular, and an increasing number of States have taken advantage of the WIN Demonstration flexibility to develop new work programs. Several States have obtained additional State funding to implement program innovations, and many have expanded services for young mothers and other potential long-term recipients.

The fact that we believe that Community Services programs are duplicative of other programs and Federal funding for them should be phased out does not relieve the Office of Community Services from its responsibilities for administering these programs effectively. We have done so over the last six years.

Question. If these programs remain, how would you improve them?

Answer. In the refugee targeted assistance program, we have sought improvements through monitoring, consultation, and corrective actions, and would expect to continue to do so. While the WIN Demonstration programs have helped us learn a bit about the efficacy of different program models, we believe improvements to the WIN Demonstration model are needed. For that reason we support the AFDC Employment and Training Reorganization Act, introduced as H.R. 3200 and S. 1655. This legislation includes not only some of the best features of the WIN Demonstration program, such as broad State flexibility and welfare agency administration, but it also incorporates some needed improvements, such as changes in Federal exemption rules for parents with children under age 6, participation standards, special school requirements for teen parents, and more realistic funding.

For Community Services programs, we will continue to assist the States and other recipients of Federal funds to improve their program operations by providing training and technical assistance at the time of on-site project monitoring visits. We will also continue to provide support to the National Association for State Community Services Programs for a project that assists the States in the development of administrative and management information systems and provides for a clearinghouse for technology transfer and transfer of best practices. We will also be implementing a program of training and training assistance to strengthen the programmatic and management capabilities of community action agencies which are the primary recipients of CSBG funds at the local level. This program will provide support for the State, regional and national associations familiar with the training needs of community actions agencies (CAAs) and will assist these associations to develop and implement training programs to increase management and program effectiveness.

## OVERALL IMPACT OF ANTI-POVERTY PROGRAMS (CONTINUED)

Question. Can you point to specific examples of initiatives your agency has taken to help families break the cycle of poverty?

Answer. All aspects of the refugee program are intended to help refugees become employed and self-supporting in order to avoid their entering into a cycle of poverty after their resettlement in the United States. The largest-scale single project in recent years has been the California Refugee Demonstration Project (RDP) which seeks early refugee entry into the labor market through mandatory services, acceptance of job opportunities, and supplementary assistance.

Since 1981, we have been actively supporting State efforts to increase employability of AFDC recipients, through stronger work programs, and to increase the economic well-being of families headed by single parents, through stronger child support programs. In the work program area, we supported the widely publicized work welfare demonstration projects, which have been reported on by the Manpower Demonstration Research Corporation. These demonstrations showed that programs, such as work experience and job search, could be effective in improving earnings and reducing dependency among a broad range of welfare recipients.

We also have supported a number of demonstration projects in States to test the extension of work program requirements to parents with young children. These projects showed that those with young children could be as successful in finding and keeping jobs as other welfare recipients. These demonstrations have provided support for legislative proposals such as the AFDC Employment and Training Reorganization Act, which the Administration endorses. In the child support area, we strongly supported the 1984 amendments and have been working vigorously with States and outside organizations to improve State performance on paternity establishment and child support collections. One example of an initiative undertaken in this area is our IV-A/IV-D interface project to improve child support performance for welfare cases. This initiative encompasses the promotion of pilot and demonstration projects, issuance of "best practice" materials, and related efforts. Another example is our promotion of using credit bureaus as a child support enforcement technique.

The major initiative which the Office of Community Services (OCS) funds each year and which is designed to help poor individuals and families break the cycle of poverty is the CSBG Discretionary urban and rural community economic development program. This program requires either job creation or the creation of business opportunities for low-income individuals. For Fiscal Year 1988, the Department will make grants totaling approximately 18.0 million dollars in this program category.

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## QUESTIONS SUBMITTED BY SENATOR QUENTIN N. BURDICK

### HEALTH CARE IN RURAL AREAS

Question. What do you propose we do to provide essential physician services such as obstetrics in rural areas without the National Health Service Corps?

Answer. First, let me make it clear that the budget request for the NHSC reflects the progress that this Department has made in placing large numbers of obligors in private practice or as salaried clinic physicians in underserved rural and urban areas.

In addition to the placement of many remaining NHSC Scholarship obligors during FY 1989, the NHSC program expects to recruit from 100 to 300 volunteer practitioners from the private sector to serve in underserved areas. This recruitment effort will be aided by the initiation of the Federal and State Loan Repayment programs during FY 1988.

It is important to look to States as well as the Federal government to solve recruitment and placement problems of physicians in rural areas. Many States train large numbers of obstetrician gynecologists in tax supported medical schools and are successful in retaining them in those States and in many cases in rural areas.

Malpractice insurance rates are another important part of the problem of recruiting and retaining obstetrician gynecologists in rural areas. We recently have issued a comprehensive report on this subject as well as a model state legislative act incorporating all recommendations. We believe that any State that passes this act or an act similar to it will resolve many of the malpractice problems that are driving qualified physicians away from deliveries.

Question. One of the duties Congress gave the Office of Rural Health Policy is to provide an impact analysis of Medicare and Medicaid regulations on small rural hospitals. This requires the Office of Rural Health Policy to work closely with the Health Care Financing Administration. How is the Office of Rural Health Policy coordinating with HCFA on this impact analysis?

Answer. The Office of Rural Health Policy is reviewing all HCFA regulations that affect small rural hospitals and other rural health care providers. We are working on ways to improve this review process and to strengthen other areas of collaboration between HCFA and the Office of Rural Health Policy. As part of this effort, we are developing a formal Memorandum of Understanding between HCFA and the Office of Rural Health Policy which will clearly define their joint responsibilities on rural health issues. Staff from HCFA and the Office of Rural Health Policy meet regularly to discuss the regulations that affect rural providers and other issues that require close coordination between the two staffs. In addition, HCFA has detailed two staff members to the Office of Rural Health who are helping to develop the relationship. We expect the relationship to improve over time and welcome your continued interest in our progress.

Question. My last question concerns Rural Health Clinics. When the Rural Health Clinic Services Act of 1977 was passed, it was estimated that there would be about 2,000 Rural Health Clinics by 1990. Yet today there are just over 400 Rural Health Clinics. What, if anything, is the Department doing to advertise this program and encourage the establishment of more Rural Health Clinics? What do you think could be done to insure the creation of more Clinics in rural areas?

Answer. The Rural Health Clinic Services Act of 1977 added rural health clinics services as a new benefit under Part B of Medicare and as a mandatory benefit of State Medicaid plans in States that permit physician assistants and nurse practitioners to practice under general physician supervision. Information about the Act is available from the Health Care Financing Administration, Medicare Fiscal Agents and the Office of Rural Health Policy. The program is available to clinics that are eligible and that apply. Rural health clinics have flourished in some States while doing less well in others. In some States with large rural areas, there are few or no rural health clinics in operation. Effective April 1, 1988, Congress raised the maximum amount that can be paid for a rural health clinic visit from $32.10 to $46.00. We believe this increase will help stimulate the development of additional rural health clinics throughout the country. There are other factors influencing the growth of rural health clinics such as State laws that limit the services which can be provided by physicians assistants and nurse practitioners. The Office of Rural Health Policy is studying these factors and will report to me on how best to promote the growth of rural health clinics in those rural areas where they are most needed. We will be pleased to provide this report to you when it becomes available.

## RURAL HEALTH DEMONSTRATIONS

One provision of the FY 87 Reconciliation bill mandates that the Health Care Financing Administration set aside 10% of its research and demonstration funding for projects related to rural health care.

I understand there has been some confusion in the Department about whether that set-aside funding was intended for demonstrations only, or demonstrations and research. I want to let you know that the 10% set-aside was intended to apply to both HCFA research and demonstration projects.

As you know, HCFA is also required to furnish a detailed report on expenditures for rural research and demonstrations.

Question. Can you tell the Subcommittee what is the status of spending on rural health research and demonstration projects?

Answer. Following the implementation of the Medicare hospital prospective payment system, HCFA initiated a number of projects designed to examine issues related to hospitals located in rural areas. Included among these studies were the following:

- Sole Community Hospitals (Brandeis Research Center, $64,500) -- Report sent to Congress on November 27, 1987.
- Uncompensated Care Costs in Large Rural Teaching Hospitals (Brandeis Research Center, $132,000) -- Results used in "Rural Teaching Hospitals and Referral Centers" report sent to Congress on February 9, 1988; also used for "Uncompensated Care" report currently in clearance in the Department.
- Urban/Rural Payment Differentials under DRGs (Brandeis Research Center and ABT Associates, $244,000) -- Report sent to Congress on December 24, 1987.
- Long Term Impact of PPS on Rural Hospitals (Brandeis Research Center, $32,285) -- Completed; used as theoretical basis for annual reporting as part of PPS Impact Report.
- PPS Impact on Rural Hospitals (Center for Health Economics Research, $344,000) -- Completed; no Report to Congress required.
- Longitudinal Studies of Local Areas Hospital Use (University of Michigan, $214,000) -- Completed; no Report to Congress required.
- Rural Secondary Specialty Demonstration (Lake Region Hospital (Minnesota) and Evaluation Mathematica, $144,164) -- Continuing.

We are also funding the following projects focusing primarily on health care in rural areas:

- Preventive Health Services for Medicare Beneficiaries (University of Pittsburgh, awarded effective May 1, 1988, projected total funding $1,345,485) -- Continuing; sites are located in rural areas.
- Economy and Efficacy of Medicare Reimbursement for Preventive Services (University of North Carolina,

projected total funding $1,674,522) -- Continuing; approximately one-third of sites are in rural areas.

- Evaluation of National Rural Swing Bed Program (University of Colorado, initially awarded in September, 1983, project funding is being continued to respond to OBRA 87 mandate, $1,181,824) -- Continuing; results used in Report sent to Congress on February 5, 1988.

HCFA will have spent approximately $5.5 million on these projects, as follows:

| | |
|---|---|
| FY 1983 | $722,000 |
| FY 1984 | $290,000 |
| FY 1985 | $671,000 |
| FY 1986 | $651,000 |
| FY 1987 | $625,000 |
| FY 1988 | $623,000 |
| FY 1989 | $837,000 |
| FY 1990-1991 | $946,000 |

In addition to these discrete projects, HCFA funds several large program evaluation efforts that focus on health care issues across settings. Included among these studies are (1) the ongoing study of the impact of PPS on hospitals, beneficiaries, quality and access to care; and (2) a series of studies designed to assess the issues of quality and access to care since the implementation of PPS, and to improve the methods we use to measure quality and access. These large program initiatives have, as one of their focuses, health care provided in rural areas.

To address the mandate in the FY 1987 Omnibus Budget Reconciliation Act (section 4403), we plan to obligate 10 percent of the total obligations for new research and demonstration projects that relate substantially or exclusively to rural health care issues. In FY 1989, assuming an appropriated budget level of $32 million, we estimate that $6.6 million will be available to fund new projects; of this amount, $660,000 would be targeted for new rural health care research/demonstration projects (in addition to the continuation of the ongoing projects included in the list above).

Specific steps we have taken to more clearly focus our research agenda on rural health care issues include the following:

- Discussions with the Office of Rural Health Policy regarding potential areas of future research and demonstrations;
- Increasing the emphasis on rural health care issues in our statement of funding priorities and solicitation for new projects for FY 1989; and
- Convening a panel of experts in the field of rural health care research in late summer/early fall 1988 with the goal of establishing a coordinated agenda of

**research and demonstration initiatives that will target specific rural health care issues for study.**

**Although our ability to meet the proposed target spending level is directly dependent on receiving high quality, technically acceptable, and relevant applications, we are confident that these efforts will allow us to be responsive to the mandate.**

## QUESTIONS SUBMITTED BY SENATOR DANIEL K. INOUYE

### REFUGEE AND ENTRANT ASSISTANCE

Question. In FY 88 Congress appropriated $26,231,000 for the States' administration of the Refugee and Entrant Assistance program. $21,569,000 was requested by your Administration for FY89. How you do justify this cut of $4,662,000 in light of the already skeletal crews with which the States are required to implement the Refugee and Entrant Assistance program?

Answer. The amount requested is based on the reduced number of 51,000 refugee arrivals that the budget projects for FY 1989. Furthermore, the skeleton staffs resulted from having to take most of the cut over the last 6 months of 1988 whereas, States could plan for the FY89 amount and better use the available resources.

Question. In your justification, you reiterate your philosophy of shifting the focus of this program from one that provides social services to one that provides employment services, including employment and skills training, job placement and classes in English as a second language. This is evident through your decreased funding request for the social services. However, I would like to know where (i.e., what account) you have requested an increase in funds, to balance the decrease in social services funding, for these employment skills services you refer to?

Answer. The total amount requested for social/employment services is based on the reduced number of arrivals anticipated by the budget and on the overall limitations on funds under the deficit reduction budget compromise agreement.

Question. How much in federal funds are appropriated for this purpose?

Answer. The amount appropriated for refugee social/employment services in FY 1988 is $65,694,000.

Question. Will there be any discretionary funds made available as an incentive to States to develop innovative programs in line with your job training and placement philosophy?

Answer. We would continue to expect to use about 15 percent of the appropriation for services for discretionary projects, principally for grants to States for innovative activities intended to reduce dependency, increase refugee employment, and encourage refugee resettlement in communities with favorable economic opportunities.

Question. In FY 88, Congress appropriated $5,840,000 for preventive health care within the Refugee and Entrant Assistance program. In light of the continuing widespread prevalence of Hepatitis B, Tuberculosis, and a host of other personal health problems well-documented in this newly arrived refugee population, on what basis do you justify a near 50 percent cut in your FY 89 request?

Answer. The decrease reflects the budget estimate of 51,000 admissions and the expectation that most of the preventive health program costs will be picked up by Medicaid and the refugee medical assistance program. Refugee and Entrant Assistance program will cover those preventive health program costs not picked up by Medicaid.

Question. Hawaii, in light of its location in the Pacific has a high number of Southeast Asian refugees relative to other States. Many Southeast Asian refugees have active tuberculosis and hepatitis which is prevalent in their region of the world. What efforts are you taking to target high risk areas, like Hawaii, who are in need of additional funds to provide treatment to these newly arrived refugees such that the disease does not spread?

Answer. Hawaii participates in the Health Program for Refugees (HPR), which is administered by the Centers for Disease Control, Public Health Service. The HPR provides modest funding for State and some local health departments to assist in providing health assessments, which include tuberculosis screening, to newly arrived refugees so that referrals for follow-up treatment can be made. In FY 1987, Hawaii received a grant of $58,399 for the HPR, including $3,936, for the hepatitis B screen and vaccination program for refugees who arrived in the U.S. after fiscal year 1981. Under this program, eligible pregnant women are tested for hepatitis B, and if they are found positive, their infants and susceptible close household contacts are vaccinated against the disease. Needy refugees are also covered by fully federally funded Medicaid and refugee medical assistance programs during their first 24 months in the United States. Hawaii claimed and received Federal refugee funding of $462,000 for such medical assistance in FY 1987.

## ASSOCIATE COMMISSIONER FOR NATIVE AMERICANS

Question. Last year the Older Americans Act authorized the new position of the Associate Commissioner for Native Americans. The Committee understands that a "hold" has been placed on hiring for this position. Is this correct? If so, what plans are being made for fulfilling the Congressional intent?

Answer. The Administration has every intention of carrying out the Congressional mandate to establish a new Office of American Indian, Alaskan Native and Native Hawaiian Programs within the Administration on Aging. This new office will be headed by an Associate Commissioner, as specified in Sect. 107 of the Older Americans Act Amendments of 1987 (PL 100-175).

A proposal to establish the new office has not been put on hold and is currently under review in the Department.

In the interim, Dr. J.T. Garrett of the Indian Health Service has been detailed to AoA as Special Advisor to the Commissioner on Aging. Dr. Garrett is a member of the Eastern Band of the Cherokee Tribe and a member of the Commissioned Corps of the U.S. Public Health Service. Dr. Garrett is assisting the Commissioner in preparing plans for the new Office of American Indian, Alaskan Native and Native Hawaiian Programs. Dr. Garrett is also assisting in development of various reports and studies on services for older Indians which were mandated by PL 100-175, and as liaison with tribal organizations and other Federal Departments and agencies serving Native American Elders.

## COMMISSIONER ON AGING

Question. Commissioner Fisk: It was the intent of Congress in enacting the Older Americans Act Amendments of 1987 that you will be reporting directly to the Secretary, rather than to the Assistant Secretary for Human Development Services. The Committee understands, however, that directly contrary to the intent of Congress that regulations are still being drafted affecting your program by individuals who do not report directly to you. Is this correct? If so, have you appealed the matter directly to the Secretary yet?

Answer. The draft regulations implementing the Older Americans Act Amendments of 1987 were prepared by AoA staff and submitted directly for review and clearance by DHHS prior to their publication in the Federal Register on March 29, 1988. No persons other than AoA staff were involved in the development of these draft regulations.

Similarly, AoA staff are currently reviewing the comments submitted on the March 29 draft regulations and will be responsible for preparing and issuing the final version of these regulations.

## PLACEMENT OF THE ADMINISTRATION ON AGING

Question. The Committee also understands that a task force has been created within the Department to "study" the placement of AoA. This development appeared in the April 1, 1988 Older Americans Report. Were you aware of this development prior to it becoming public? What input did you have in determining its composition, mission, etc?

Answer. The report of a Task Force in the Department by the Older Americans Report was incorrect. There is no such Task Force. The Secretary has directed the Assistant Secretary for Management and Budget to undertake a study of organizational and support matter raised by the recent amendments to the Older Americans Act. I have been assured that AoA will be consulted throughout the study.

## AGING STAFFING NEEDS

Question. Ms. Commissioner, it has also come to the Committee's attention that there are critical staffing shortage within your Administration. For example, the Committee understands that currently there are three divisional management positions vacant, which represents 50% of your total divisional management positions. We would appreciate learning your views on the effect this has on your programs and whether the Administration appears supportive of efforts to fill these positions.

Answer. The management duties and responsibilities normally carried out by the incumbents of these positions are being assumed by second level supervisors (Office Directors) until such time as funding and employment ceilings allow the positions to be filled.

## HEALTH PROMOTION/DISEASE PREVENTION PROGRAM

Question. Ms. Commissioner. This past year the Committee included approximately $1 million for your Health Promotion and Disease Prevention initiatives. The committee expected your administration to work closely with our nation's schools of public health in this regard. At this time we would appreciate a report describing your plans for spending these funds.

Answer. The conference report on the Continuing Resolution calls for $957,000 of Title IV funds to be spent by the Administration on Aging for health promotion and disease prevention initiatives. No additional specifics are provided. Section 422 (a)(2) authorizes the Commissioner on Aging to award grants to "institutions of higher education having graduate programs with capability in public health, the medical sciences, psychology, pharmacology, nursing, social work, health education, nutrition, or gerontology for ... prototype health education and promotion programs for use of State and area agencies on aging in implementing preventative health service programs."

The Fiscal Year 1988 published AoA priority areas for discretionary funding include priority area 9.3B, "Education for Self Care." This priority area calls for the development of "model programs that will educate older persons to take a more active role in the management of their health care." These projects are asked to teach older persons about "how to prevent ... illness and maintain optimal health." These projects are required to involve State Aging and Health Agencies. AoA has received and is reviewing 16 applications under this priority area from institutions of higher education with the capabilities listed above including several involving Schools of Public Health.

I have made a commitment to fund at least $957,000 worth of proposals that meet the provisions of Section 422(a)(2).

## ELDERLY NATIVE HAWAIIAN PROGRAM

Question. In the Older Americans Act reauthorization legislation that passed last year, a new provision was adopted to make available grants for elderly Native Hawaiian programs, contingent on appropriations for the Indian grants program equaling or exceeding 110 percent of FY 1987 appropriations. FY 1988 appropriations fell just short of this amount and there has since been discussion about reprogramming funds to meet this trigger level. Can you tell me the status of these discussions and whether we can expect funds to be available for the Native Hawaiian program this fiscal year?

Answer. The Administration received a Congressional request to consider reprogramming for Title VI purposes a line item amount of $957,000 related to ombudsman activities which appeared in the FY 1988 appropriation. The request was based on the fact that the appropriation language posed difficulties of reconciliation with the language of the authorizing legislation. At the time the Congressional request was received, the funds had already been made available to State Agencies on Aging under the Title III Part B authority of Section 303(a)(1). Therefore, there was no possibility of considering the reprogramming request. There presently is no indication that funds will be available this fiscal year for the Native Hawaiian program.

## NATIVE HAWAIIAN REVOLVING LOAN FUND

Question. Last year funds were made available for the newly authorized Native Hawaiian small business loan program. The Committee would appreciate a report on your efforts to implement this program as well as your views as to whether a similar program should be instituted for American Indians.

Answer. The Department is moving rapidly to implement the Native Hawaiian Revolving Loan Fund (RLF) demonstration project. On January 22, 1988 the Department published in the Federal Register a Notice of Intent (NOI) to develop regulations for the RLF. The public comments which were received in response to the NOI were used in developing the Interim Final Regulations (IFR), which are being cleared within the Department. The program announcement which will solicit applications to administer the RLF is also in clearance. It should be published in the Federal Register at approximately the same time as the IFR and will give applicants 60 days to develop and submit their applications. These activities will permit the Department to award the grant before the end of the current fiscal year.

This Department would oppose creation of a similar program for American Indians for two reasons. The Department of the Interior's Bureau of Indian Affairs (BIA) already has a loan program of this type under the Indian Financing Act which has broader lending authority and allows more capital investment. A loan fund established and administered by this Department would be duplicative of the BIA effort which loaned $7.5 million in 1987. In addition, the Administration has proposed no funding for the Native Hawaiian RLF in the FY 1989 budget. We prefer instead to make these funds available in the form of ANA grants which promote social and economic self-sufficiency for a larger pool of eligibles including American Indians, Native Hawaiians, and Alaskan Natives.

## OFFICE OF HAWAIIAN AFFAIRS (OHA)

Question. Concern has been expressed by the Office of Hawaiian Affairs of the State of Hawaii that they have not been able to submit grants to your agency exclusively because they are a state agency. The Committee last year directed the Administration to allow such submissions. Accordingly, we would appreciate your providing the Committee with a report on the status of this matter.

Answer. In the past, ANA has taken the position that funding of public agencies would divert limited program dollars from Tribes and community-based organizations to entities which are supported by public funds.

We have recognized, however, the unique situation of the Office of Hawaiian Affairs, and on a case-by-case basis, ANA has in fact funded worthy projects submitted by OHA. Since 1983 OHA has received almost $300,000 in ANA funds. In that year, they were awarded a 3-year grant totaling $201,896. In FY 1987 OHA was funded again, for $96,973, to provide training and assistance to Native Hawaiians building their own homes. In summary, OHA has received funds in four of the last six fiscal years. We believe this compares favorably with the funding history of ANA grantees in general.

We will consider this matter as we develop the Federal Register announcement for FY 1989 funding.

### AMERICAN SAMOANS IN THE UNITED STATES

Question: For several years the Committee has directed the Administration to work closely with the U.S. Department of Labor and the U.S. Department of Education in order to effectively address the many pressing needs of American Samoans, and in particular those residing in the State of Hawaii. The Committee is interested in learning what steps OHDS has taken in response to these directives.

Answer: The Office of Human Development Services published a Coordinated Discretionary Funds Program Announcement for fiscal year 1988 in the Federal Register on December 30, 1987. The Announcement includes a priority area specifically addressing the human service needs of American Samoans residing in the United States. OHDS anticipates funding several 24-month projects, at a funding level of $50,000 per year for each project. Eight applications were received under this priority area, and after panel review, final funding decisions will be made.

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## QUESTIONS SUBMITTED BY SENATOR LOWELL P. WEICKER, JR.

### FAMILY PLANNING

Question. Mr. Secretary, as you know, I have been very concerned about family planning regulations that were issued this past year. While the courts are considering these regulations, does the Department have any other plans to change the family planning program either through legislative proposals or Administrative regulations?

Answer. The Department will soon send proposed legislation to Congress which would change the categorical family planning program to a State Administered Grant Program. The Administration's FY 1989 Budget Request reflects this proposal. There are currently no other legislative proposals or administrative regulation changes being planned.

## HEALTH PROFESSIONS TRAINING PROGRAMS

Question. Mr. Secretary, once again I am very concerned about the Department's efforts to essentially gut federal funds for the Health Professions Training Programs. First, I would like to ask you, do you believe the federal government should have a role in ensuring availability of health care services by qualified health professionals?

Answer. The Federal Government has the role in the national health care system to provide direction, establish national health policy, and carry out enacted legislative provisions. Over the past 2 decades the Federal Government has provided funds to health professions schools to develop, operate and maintain quality health education programs in educational institutions. When there was a projected shortage of health professionals in the 1960s and 1970s, we provided financial assistance to students to pursue health careers so that we now have adequate supplies of health professionals in most categories.

HRSA is now directing its efforts to ensuring and enhancing the quality of health care. We are proposing to implement the Health Care Quality Improvement Data Bank of medical and dental malpractice settlements, judgments and professional disciplinary actions and the Health Care Improvement Fund which will sponsor research on the efficacy of new medical technologies and treatments. In addition, the new program of Cooperative Health Professions Initiatives will provide targeted assistance to help meet high priority health personnel needs including the education of selected types of health professionals.

Question. Why then does the Department propose to cut more than $170 million from such training and propose a small $40 million program that clearly is not enough to do the job?

Answer. We have proposed a new legislative authority that will enable us to target our limited resources to areas of greatest need.

The Cooperative Health Professions Initiatives program would allow non-Federal entities increased independence and broadened options in developing health professions programs to meet particular State, local, or regional needs. Needs should be identified primarily by the States and other non-Federal institutions and agencies that are most familiar with local and regional needs and available training resources. We would place heavy reliance on the help of non-Federal groups in the planning of necessary types of aid and expect long-range financial support to come from State and local governments.

## TWO YEAR BUDGET REQUEST

Question. Mr. Secretary, why did the Department submit a budget request for FY 1989 and FY 1990? Particularly in the area of health and science, how did you make a determination of what we will need by way of funding 2 years from now? For example, how did the Department decide that the NIH should receive a 5.4% increase in non-AIDS research for FY 1989 but only a 1.9% increase for FY 1990?

Answer. The Administration and Congress developed the "Bipartisan Budget Agreement", a two year plan of deficit reduction. To show the Administration's commitment to the goal of deficit reduction and willingness to support that compromise it is proposing a two year budget. This would permit more time for consideration of spending decisions. It was agreement which set dollar goals and approved function allocations between national security and domestic spending. Following this plan, the Department would achieve Gramm-Rudman-Hollings Act targets for fiscal years 1989 and 1990.

## CONSOLIDATED AIDS FUNDING

Question. Secretary Bowen, last year this committee rejected a proposal to consolidate all of the AIDS funding under the Office of the Secretary. Why has the Department proposed to consolidate all AIDS funding under the Office of the Assistant Secretary in FY 1989?

Answer. There are several reasons for requesting all AIDS resources in a single account.

The single account concept will provide for a greater degree of flexibility to meet changing requirements. AIDS research is dynamic making it difficult to predict exactly where science will be several years in advance, as required by the budget process. We believe that the consolidated account concept will allow PHS to reallocate resources to meet emerging needs with greater ease.

Consolidation of AIDS funding will allow greater coordination across the agencies of PHS. For example, currently at the National Institutes of Health alone, sixteen components are involved in different aspects of AIDS research and prevention are pursued, to foster better interagency communication, and to avoid unnecessary duplication.

Centralization of resources will promote the degree of visibility in the budget process that is commensurate with the high priority placed on the AIDS epidemic by the Administration.

Question. Are you concerned that such a consolidation may slow the efforts of our scientists and public health experts at a time when many of us are trying to expedite these activities?

Answer. While the coordination of the PHS AIDS effort has been excellent, we believe that the consolidation of the AIDS account would afford PHS a better system for coordinating and allocating AIDS resources.

Our AIDS request proposes having a contingency of $15 million to be withheld from initial allocation. This contingency fund allows PHS additional flexibility and would afford PHS a funding mechanism to provide immediate allocation of resources in response to any urgent request for additional AIDS resources.

Additionally, we are proposing a general provision that would allow the transfer of up to 3 percent from any PHS appropriation (except Retired Pay) to the AIDS account. The purpose of our proposal which is to increase our flexibility to manage the total AIDS effort and to be more responsive to changing priorities resulting from new opportunities including scientific breakthroughs in AIDS research and prevention. Current reprogramming rules and procedures for shifting (non-AIDS) resources within an appropriation are very restrictive and require considerable time. We believe that our proposal would serve to expedite the process of allocation of AIDS resources.

## FY 1989 BUDGET REQUEST

Question. The discretionary programs administered by the OHDS are recommended in the President's budget to be level appropriated in FY '89. What was the original budget request to the Department and how does it compare to the request before the Subcommittee?

Answer. The original budget request to the Department of $6.4 billion was completed before the Bipartisan Budget Agreement was reached and therefore does not directly relate to the current request of $6.2 billion before the Subcommittee.

Question. What was the Department's original budget request to the OMB for the OHDS?

Answer. The Department's original request tc the OMB was $5.9 billion.

Question. How will these services be maintained at the current level if the funding remains frozen?

Answer. The Office of Human Development Services has been able to continue service levels in the past at level funding. Examples of how this has been accomplished include using the Cost Study of selected Head Start grantees to determine if there are efficiencies that can be made, or if grantees can redirect funds within current funding . The Administration on Aging has continually provided increased services by implementing management improvements and encouraging increased contributions by those elderly participants who are able. The OHDS will continue to pursue these and other management improvements in order to provide services.

## PROGRAMS FOR THE FRAIL ELDERS

Question. The National Institute on Aging estimates that between 2.5 and 3 million Americans have Alzheimers disease and that the care for these individuals costs nearly $90 billion per year. Late last year the Congress established a new program targeted to assist elderly individuals, and their families, who are afflicted with a physical or mental disability, with neurological or organic brain dysfunction, such as Alzheimers disease. The in-home services for frail older individuals program will disperse grants to states for the provision of special services for these frail elderly individuals and their families in order to prevent premature institutionalization. As you know, Congress provided $4.8 million in fiscal year 1988 for the start-up of this new program.

What has OHDS done to implement this new program?

Answer. In order to assure proper implementation of the new Part D, we have asked States to amend their State Plans by providing us with assurances that they will carry out the program in conformance with the new requirements of the Act. Upon receipt of these State Plan assurances, we have released Part D funds to the States. All 50 States and three jurisdictions have submitted the required State Plan assurances and have received funding. A total of $4.75 million of the $4.78 million appropriated has been allocated to the States. The remaining funds will be allocated as soon as the remaining jurisdictions submit their State Plan assurances. Award of the funds to Area Agencies is carried out according to the procedures which each State establishes. One of the requirements for the States is to develop eligibility criteria for services under this new part.

## ALZHEIMER'S SUPPORT

Question. The National Institute on Aging estimates that between 2.5 and 3 million Americans have Alzheimers disease and that the care for these individuals costs nearly $90 billion per year. Late last year the Congress established a new program targeted to assist elderly individuals, and their families, who are afflicted with a physical or mental disability, with neurological or organic brain dysfunction, such as Alzheimers disease. The in-home services for frail older individuals program will disperse grants to states for the provision of special services for these frail elderly individuals and their families in order to prevent premature institutionalization. As you know, Congress provided $4.8 million in fiscal year 1988 for the start-up of this new program.

Given the tremendous difficulties facing victims of Alzheimer's Disease and the fact the [Title III-D] program is authorized at $26.2 million in FY 89, what is the Department's justification for level funding for this new program?

Answer. The Department's FY 1989 request for funds for Title III-D services is consistent with the efforts of the Bipartisan Budget Agreement. I should note in this connection that, in allocating resources to the provision of in-home services to frail older persons, States are not limited to the funds available under Title III, Part D. States may also use Title III, Part B (Supportive Services and Senior Centers) funds for this purpose, depending on the degree of need determined by the individual State Agencies on Aging for their respective States. While the proportion of Title III-B funds allotted to in-home services may vary from one State to the next, we have no doubt that States will continue to use their Older Americans Act resources to address pressing, priority needs.

## DISCRETIONARY CONSOLIDATION

Question. Last year, the President requested in his budget for OHDS a generic appropriations for discretionary programs administered by your office. As you know, Congress did not agree with that request. This year the budget does not contain the "generic appropriation". However, it does include a request to consolidate the research, training and demonstration programs associated with the discretionary social services program activities. What is the purpose of the consolidation request?

Answer. The purpose of the consolidation is to highlight the total committment of OHDS to research, training and demonstration activities by displaying the request as one line item in the budget. In the justification material each program is seperately identified along with the proposed funding level for that program. Current authorities and seperate funding will continue.

Question. What criteria would the OHDS use to determine funding levels for the catagorical programs under this section?

Answer. Funding levels have been determined and are identified in the justification material provided to the Congress. These levels were determined by previous appropriation levels, with no program receiving a funding level less than the 1988 appropriated level.

Question. What assurances can you give the Subcommittee that each category would be funded adequately?

Answer. OHDS has identified the proposed funding level for each of the categorical programs in the budget justification to the Congress. As usual, if OHDS were to propose a different distribution at a later date the Congress would receive a reprogramming request.

## RUNAWAY AND HOMELESS YOUTH PROGRAM

Question. Your budget justification indicates the Runaway and Homeless Youth Program will devote "additional effort to provide on-site training to shelter staff to address critical hazards to street youth, including sexual exploitation, AIDS and Drugs". Would you briefly described the training programs provided in each of the identified hazard areas and how much was spent on this activity in FY 1988?

Answer. We are launching a single training activity that will encompass all three topics as they relate to the central issues of AIDS among street youth. The national training program on AIDS will be conducted in every community where the Runaway and Homeless Youth Program funds a center. The training will be on-site so we can be sure that it reaches all the volunteers and all paid staff who work directly with youth. Staff of other youth-serving agencies in the community will be invited to attend the training on a space-available basis.

We are planning to spend $603,000 on this activity in FY 1988.

Question. How much do you plan to spend in FY 1989?

Answer. The expenditure for FY 1989 will equal the FY 1988 amount: $603,000.

## SERVICES FOR DISABLED ELDERLY

Question. What kinds of projects would the Department initiate if we were to appropriate $1 million for FY 1989 to conduct demonstration projects to coordinate the State Agency on Aging long-term care ombudsman program with the State protection and advocacy systems for the developmentally disabled and mentally ill?

Answer. The Administration on Aging will implement all programs for which funds may be appropriated in accordance with applicable statutory authorizations. However, I would like to point out that, under the 1987 Amendments to the Older Americans Act, funds to implement Section 427 would not become available unless additional funds were appropriated. These additional funds, in the aggregate, would have to exceed 105 percent of the previous year appropriation for Title III (other than Sections 306(a)(6)(P), 307(a)(12), 311, and Parts E, F, and G); Title IV (other than Sections 427 and 428); Title V and Title VI.

## PROTECTION AND ADVOCACY

Question. Your budget proposes a freeze at the FY 1988 funding level of $19.1 million for protection and advocacy services for developmentally disabled individuals, although the authorized level for FY 1989 is $22 million. As you know, this program represents the only source of federal funding to protect our most vulnerable citizens from abuse and neglect. When we know that protection and advocacy agencies are currently unable to meet the existing demand for assistance to disabled individuals, what is the justification for denying this program any increase in FY 1989?

Answer. The appropriation for FY 1988 represented a $3.648 million increase over the appropriation from the preceding fiscal year. Consequently, consistent with the Bipartisan Budget Agreement no increase is requested.

## DEVELOPMENTAL DISABILITIES STATE GRANTS

Question. Your budget request for FY 1989 proposes to freeze the funding level for the developmental disabilities state grant at the FY 1983 level of $58.4 million, well below the authorized level of $69.9 million. At your proposed level, there will be no additional funds available to assist states in meeting the new responsibilities imposed as a result of the reauthorization last year. Specifically, the amendments we passed require states to focus additional efforts on serving those disabled individuals who are either unserved, or under-served by state programs. In the absence of an increase in funding, how will states be able to implement their new responsibilities without reducing their ongoing efforts to plan, evaluate and monitor the provision of services to disabled persons?

Answer. In fact the appropriation for FY 1988 does itself represent an increase of $1.901 million over the FY 1987 level. This increase should be sufficient to implement the new requirements of the law by taking advantage of already existing channels for collecting information and delivery of services. Particularly, advantage will be made of the national organizations representing the developmental disabilities community, such as the National Association for Developmental Disabilities Councils, to coordinate efforts that would otherwise be duplicative from state to state.

## UNIVERSITY AFFILIATED PROGRAMS

Question. I note that your budget request includes funding for the university affiliated facilities and programs of national significance under a new account called human services research, training, and demonstration. You also state that categorical funding will be continued at last year's levels for these two activities. Will these programs continue to be administered by the Administration on Developmental Disabilities?

Answer. Yes, the Administration on Developmental Disabilities will continue to administer the University Affiliated Programs and Projects of National Significance.

## COMMUNITY SERVICES BLOCK GRANT PROGRAM

Question. Mr. Secretary, in many ways the President's budget request for fiscal year 1989 is a refreshing reprieve from the budgets of previous years that dramatically slashed spending for programs under the subcommittee's jurisdiction. However, in past years, the President's budget proposed the termination of the Community Service Block Grant Program over a four-year period. This proposal repeatedly has been rejected by the Congress. Why then does the President persist with trying to eliminate this program which provides Federal resources to local communities for services to combat poverty?

Answer. We believe the services and activities funded under the Community Services Block Grant (CSBG) are both similar to and duplicative of services offered under other programs. We believe that States have the authority, under existing programs, to provide the same services as are now provided with CSBG dollars. We expect States to continue to fund CSBG activities which have been effective, or of high priority, and to generate other forms of local or private support to maintain services. To allow time for States to develop these alternative sources of support, we are proposing a gradual phase-out of the CSBG program over a four-year period.

## Funding for Low Income Programs

The budget justification argues that termination of the CSBG program is warranted because it is duplicative of other federally funded services. The justification States the programs include, the Social Service Block Grant, the Low Income Home Energy Assistance Program and Head Start. Yet there is hardly any comfort here for Low-Income Americans. The President's budget proposes to freeze funding for Head Start and the Social Service Block Grant and proposes a to 22% reduction in funding for LIHEAP. Isn't it fair to say Mr. Secretary, that under the President's FY89 budget proposal for your department discretionary spending for low income programs would fall below the fiscal year 1988 levels?

Question. Isn't is fair to say Mr. Secretary, that under the President's fiscal year 1989 budget proposal for your department discretionary spending for low income programs would fall below the fiscal year 1988 level?

Answer. In total, funding for discretionary low income programs decreases between fiscal years 1988 and 1989; however, with the exclusion of the Low Income Home Energy Assistance Program, Work Incentives, and Community Services programs, funding would increase by more than 3 percent. The Bi-partisan Budget Agreement allowed a 2 percent increase in discretionary programs.

Question. How much do you estimate spending on these programs will fall below fiscal year 1988?

Answer. Funding for discretionary low income programs under jurisdiction of this Subcommittee totals $3,059 million for fiscal year 1989. For these same programs, Congress provided $3,499 million in fiscal year 1988.

As stated above, however, if you exclude the Low Income Home Energy Assistance Program, Work Incentives, and Community Services programs from the calculations fiscal year 1988 totals $1,440 million and fiscal year 1989, $1,486 million, an increase of $46 million.

## COMMUNITY FOOD AND NUTRITION PROGRAM

Question. Questions have been raised over the process by which HHS will be awarding Community Food and Nutrition Program (CFNP) Discretionary Grants this fiscal year. Could you state for the record what kinds of agencies are eligible for grants and whether or not the Department has imposed any application restrictions on grant applications in FY 88 that differ from FY 87?

Answer. The 1987 Program Announcement for the CFNP program describes as eligible for funding, "state and local public and private nonprofit agencies with a demonstrated ability to develop and implement programs and activities similar to those described in the announcement for funding." Since the Department did not solicit new applications for funding in FY 1988 but instead used highly ranked but unfunded applications submitted in response to the 1987 program announcement, the same application restrictions imposed in that announcement continue to apply to applications for funding in FY 1988.

Question. Is the lack of staff contributing to the Department's inability to process applications for the CFNP discretionary grants program annually?

Answer. The decision not to solicit new applications for CFNP funding in FY 1988 was based primarily on having received a large number of highly ranked applicants for this program in 1987. Given such a large pool of qualified applicants and the low funding amounts, it was felt that considering the most highly ranked but unfunded FY 87 applicants would be the most efficient use of administrative resources. This also enabled us to make the grant much earlier in the fiscal year.

Question. On what basis did the Department determine it had authority to award grants for FY 88 based on applications received in FY 87? How widespread is this practice?

Answer. There is no requirement in the FY 88 CFNP legislation requiring HHS to solicit applications for funding. The Department is, however, considering the FY 87 applications competitively for funding in FY 88 in compliance with the legislative requirement and general departmental requirements.

Question. If Congress provides funding for the CFNP in FY 89, do you intend to repeat this procedure?

Answer. No. The Department would publish an announcement soliciting new applications for any CFNP funding during FY 1989.

## LIHEAP FUNDING

Question. The President's budget again proposes to dramatically reduce the Federal commitment to the Low Income Home Energy Assistance Program (LIHEAP). Congress appropriated $1.53 billion for LIHEAP in fiscal year 1988 and the President's budget for FY 1989 requests $1.18 billion over a 22% reduction. Based on the President's recommendation for fiscal year 1989, how many fewer households do you estimate will be served in fiscal year 1989?

Answer. In FY 1986, about 6.7 million households received help with heating costs. In FY 1987, slightly more households, 6.8 million, received assistance with their heating costs. Based on the States' estimates of uses of LIHEAP funds in FY 1988, as reported during a February 1988 phone survey of State LIHEAP grantees, we believe that 6.3 million households will receive assistance with their heating costs, a 7% reduction from the previous fiscal year.

Because LIHEAP is a block grant which affords the grantees flexibility in designing their energy assistance programs, there is no direct correlation between reductions in Federal appropriations and households served. The LIHEAP grantee may supplement their Federal appropriation with State or oil overcharge monies, not exercise their option to transfer funds out of LIHEAP into other block grants, eliminate a service component such as cooling or weatherization or reduce the size of the benefit provided. Because of the flexibility of the block grant, we are unable to estimate the number of households that will be served in FY 89 until the States determine the design of their FY 89 LIHEAP program.

Question. If the President's FY 89 request is approved by Congress, what would the percentage reduction in LIHEAP funding be since FY86?

Answer. The percentage reduction in Federal appropriations for LIHEAP between FY 1986 and FY 1989 would be 40%. However, the State LIHEAP programs received an influx of $186 million in oil overcharge monies in FY 1987 and estimate another $143 million in FY 1988. We expect the States to continue to utilize these additional sources of funding for energy assistance in FY 1989. Also, the percent of income low income households pay for heat has continued to decline, dropping from 5.9% in FY 84 to 5.2% in FY 87.

### LIHEAP -OIL OVERCHARGE FUNDS

Question. What percentage of the oil overcharge funds that have been allocated to the States would be necessary to offset this cut in Federal funding?

Answer. In order to offset the $344 million reduction in Federal appropriations for LIHEAP from FY 1988 to FY 1989, 10% of the funds allocated to the States would be necessary to offset this reduction. If the Federal appropriation level for LIHEAP in FY 1986 is used as a base, then 24% of the $3.4 billion in oil overcharge funds distributed to the States would be needed to offset the $822 million difference between Federal LIHEAP appropriations in FY 1986 and FY 1989.

### LIHEAP- ELIGIBLE HOUSEHOLDS

Question. What percentage of the households eligible for LIHEAP will receive assistance in FY 88 and FY 87?

Answer. The March 1987 Current Population Survey (CPS) data indicate that an estimated 24 million households had incomes under the Federal maximum standard and an estimated 17.8 million had incomes under the stricter income standards adopted by many States, and thus were eligible for LIHEAP.

Information regarding estimates of households eligible under the Federal maximum standards for LIHEAP assistance is obtained from the Current Population Survey (CPS). Many States have adopted stricter eligibility standards for eligibility. For example, in FY 1986, LIHEAP provided heating assistance to 29% of the 23.4 million households who were eligible under the maximum Federal eligibility standards which is the greater of 150% of poverty or 60% of State median income. Based on the stricter income standards adopted by many States, 37% of the 18 million eligible for LIHEAP were served. A total unduplicated number of LIHEAP recipient households can not be calculated from State reports because households could receive more than one type of assistance. Previous State estimates indicate that about two-thirds of the national total of households receiving winter crisis assistance also receive regular heating assistance. The estimates of households provided with LIHEAP heating benefits take into account this overlap when it combines heating assistance and winter crisis assistance.

Because of the flexibility of the block grant, we are unable to estimate the number of households that will be served in FY 1989, until the grantees decide on the design of their FY 1989 energy assistance programs.

Households Eligible for LIHEAP

| Fiscal Year | Eligible Households | Assisted with heating costs | Proportion of eligible receiving LIHEAP |
|---|---|---|---|
| 1982 | 22.0 m | 6.25 m | 28% |
| 1983 | 23.4 m | 6.8 m | 30% |
| 1984 | 23.4 m | 6.8 m | 30% |
| 1985 | 23.4 m | 6.8 m | 30% |
| 1986 | 23.4 m | 6.7 m | 29% |
| 1987 | 24 m | 6.8 m | 28% |
| 1988 | 24 m | 6.3 m | 26% |

## LIHEAP - AVERAGE BENEFITS

Question. What impact do you estimate the 16% cut will have on the average benefit received in FY 88 as compared with FY 87?

Answer. According to the phone survey conducted by the Office of Energy Assistance, States estimate that average benefits for heating assistance in FY 1988 were reduced by $6, a 3% reduction from the previous year.

Average Benefits - Heating Assistance

| FY 86 | FY 87 | FY 88 |
|---|---|---|
| $213 | $205 | $199 |

Question. What do you estimate the average benefit will be if the President's proposal was adopted?

Answer. Because LIHEAP is a block grant which affords the grantees flexibility in designing their energy assistance programs, there is no direct correlation between reductions in Federal appropriations and households served. The LIHEAP grantee may supplement its Federal appropriation with State or oil overcharge monies, not exercise its option to transfer funds out of LIHEAP into other block grants, eliminate a service component such as cooling or weatherization or reduce the size of the benefit provided. Because of the flexibility of the block grant, we are unable to estimate the average benefit for FY 89 until LIHEAP grantees determine the design of their programs for FY 89.

Question. What percentage of elderly households do you estimate are receiving LIHEAP funds in FY 1988?

Answer. Based on March 1987 Current Population Survey Data, about 37 percent of the households assisted with heating costs had at least one member 60 years or older, which is about the same proportion of elderly among all eligible households.

### LIHEAP - OIL OVERCHARGE FUNDS

Question. On February 24, 1988, it was announced that Texaco entered into a $1.25 billion settlement agreement as part of its obligations under the 1986 Stripper Well Agreement. Many have cited this money as further evidence to justify the cut of over $300 million in LIHEAP funds. How much of the $1.25 billion do you project will be allocated to the States and over what period of time?

Answer. According to the Department of Energy, under the terms of the agreement between Texaco and the Department of Energy, Texaco will make an initial payment of $400 million shortly after the agreement becomes final. A second payment of $190 million plus interest will be made 18 months after the agreement becomes final, and then Texaco will make four additional annual payments of $165 million each, including interest. With interest, Texaco's total payments are expected to exceed $1.5 billion. Funds paid to DOE for crude oil violations will be distributed under a formula reached in an earlier case known as the Stripper Well case. Under this formula, 20 percent of the funds are reserved to be distributed under a public claims procedure and the remainder of the funds are divided evenly between the Federal government and the States for use in energy related programs.

DOE and Texaco have developed a Consent Order which was formally proposed in the Federal Register on April 27, 1988. Before deciding whether to make the proposed consent order final, DOE will hold a public hearing on May 31, and consider written comments submitted within 30 days of the publication of the proposed settlement.

Question. Is the $1.25 billion in addition to the $3.0 billion cited in the budget justification?

Answer. Yes, the $3.0 billion in oil overcharge monies available to the States, that was cited in the budget justification for LIHEAP, referred to the $3.4 billion in oil overcharge funds that has been distributed to the States to date.

Question. How much of the remaining oil overcharge funds that have been allocated to LIHEAP do you estimate States will spend in FY 88?

Answer. Based on the phone survey of State LIHEAP grantees conducted in February 1988, the States estimate that they will obligate $143 million in oil overcharge funds through LIHEAP in FY 88.

Question. How much do you estimate will be spent in FY 89?

Answer. Based on the percentage of oil overcharge funds that have been allocated to LIHEAP in past fiscal years, we estimate that 27% of the remaining Exxon funds will be allocated to LIHEAP, or $270,000,000; 10% of the remaining Stripper Well funds or

$33,000,000 and 10% of the future Stripper Well distributions in FY 89 (i.e., Texaco) $25,000,000. These numbers represent the relative priority States have placed on LIHEAP.

Question. Based on your current estimates, what percentage of the oil overcharge funds are States allocating to LIHEAP?

Answer. According to the General Accounting Office report, Funding State Energy Assistance Programs March 1987, $38.5 million, or 19.3% of the $200 million distributed under Section 155 of P.L. 97-377, the "Warner Amendment", was expended through the LIHEAP program. The most recent quarterly report from the Department of Energy, for the period ending December 31, 1987, indicated that $796,282,969 of the total $2.1 billion distribution of oil overcharge monies under the Exxon case were accounted for in the four DOE energy conservation programs. The Fiscal Year 1986 and 1987 phone surveys conducted by the Office of Energy Assistance indicate that $184 State LIHEAP programs. Therefore, approximately 21% of the Exxon funds whose uses have been designated by the States have been designated for LIHEAP. However, the States estimate an additional $121 million in Exxon funds will be designated for LIHEAP in FY 1988 and this may increase the percentage of Exxon funds allocated to LIHEAP.

According to the Department of Energy's quarterly Stripper Well status report, States have submitted plans for use of $598,256,366 of the $993 million distributed so far. The Fiscal Year 1986, 1987 and 1988 phone surveys conducted by the Office of Energy Assistance indicate that $47,958,363 of the Stripper Well monies have been allocated through State LIHEAP programs. Since States must receive prior approval for allocation of Stripper Well funds, the States' estimates of FY 88 Stripper Well allocations to LIHEAP were included in determining this percentage. Therefore, approximately 7% of the Stripper Well funds whose uses have been designated by the States have been designated to be expended through LIHEAP.

Question. How many States are supplementing LIHEAP funds with State resources?

Answer. In FY 87, eight States reported supplementing their LIHEAP appropriations with State or other funds and 30 States supplemented their programs with oil overcharge funds. In FY 88, two States estimate that they will use State funds to supplement their LIHEAP appropriations and 27 States estimate they will use oil overcharge funds to supplement their LIHEAP program.

Many other low income programs assist with shelter costs. For example, many States provide energy assistance to non-LIHEAP low income households through Title IV-A of the AFDC program. Housing programs will assist 4.4 million households, open ended matching is available for energy assistance provided to 3.8 million AFDC households and SSI and other indexed entitlement programs include a component for energy costs and energy price increases.

## QUESTIONS SUBMITTED BY SENATOR MARK O. HATFIELD

Question. When can I expect a decision by the Appeals Council will be rendered?

Answer. The request for the Appeals Council to review the Fairview Training Center case was received in SSA's Office of Hearings and Appeals on April 25, 1988. A preliminary analysis indicated that this was a mandatory grant review case. Grant review letters were sent to the parties in May 1988, and a complete review of the case is being conducted. Since the provider, the Fairview Training Center, asked to appear before the Appeals Council, a hearing has been scheduled for September 1988. A decision by the Appeals Council could be issued 30 days after the Appeals Council hears the case.

### OREGON ICF/MR TERMINATION

In April 1987, the Health Care Financing Administration (HCFA) immediately terminated Medicaid funding to an ICF/MR in Oregon (Fairview Training Center). When Oregon asked an Administrative Law Judge to rule on the issues HCFA argued and the ALJ ruled that no administrative review existed. A subsequent judicial review in federal court ruled that the state had not exhausted all administrative review and the state recently filed an appeal with the Appeals Council. I have written Ms. Eileen Bradley, Associate Commissioner of SSA, asking for expedited review of that appeal.

Given the financial strain caused to the state because of the loss of more than $8 million which was to be used for programs to assist the developmentally disabled residents of Oregon:

Question. Are there other instances where states losing Medicaid certification have had their funding immediately terminated?

Answer. Under authority contained in Section 1910(c)(2) of the Social Security Act, the Secretary must immediately terminate funding for a facility whose conditions constitute an immediate and serious threat to the clients' health and safety.

Since the start of the ICF/MR look-behind initiative in FY 1985, this authority has been invoked only four times out of 52 notices of intent to terminate. The relatively small number of potential adverse actions (and the very small number of final terminations) is evidence of a general view that conditions in most ICFs/MR are adequate.

Question. What is your policy justification for reducing funds to a facility that cannot transfer its residents to other facilities?

Answer. Section 1910(c)(2) of the Social Security Act states in pertinent part "...any agreement between such facility and the State agency shall remain in effect until the period for filing a request for a hearing has expired or, if a request has been filed, until a decision has been made by the Secretary;

except that the agreement shall not be extended if the Secretary makes a written determination, specifying the reasons therefore, that the continuation of provider status constitutes an immediate and serious threat to the health and safety of patients (emphasis added), and the Secretary certifies that the facility has been notified of its deficiencies and has failed to correct them." Thus, we have no authority to continue to reimburse States for the cost of care for individuals when we find conditions that pose an immediate and serious threat to the residents' health and safety, as we did at Fairview.

Question. The Department's FY '89 justification for refugee and entrant assistance indicates the purpose of the activities unde the refugee and entrant program is to ease the refugees' adjustment to American society and to allow them to become "independent and self sufficient in the shortest time possible".

Yet, while claiming the goal of easing refugees' adjustment, the budget proposes to cut cash and medical assistance by 12%, social services by 54% and preventive health by 48%. How will cutting the program ease refugees' adjustment in the United States?

Answer. The budget is based on lower refugee admissions and a shorter period of federal reimbursement than prior years. Within those constraints, its adequate to maintain services and assist refugees to assimilate and become self-sufficient.

Question. How do you anticipate the State refugee programs will cope with the proposed 17% cut in State administration and the 54% cut in social services?

Answer. Our FY 1989 budget request proposes that funding for State administration continue to equal approximately 12 percent of the cost of cash and medical assistance. This maintains the percentage set by Congress in the FY1988 Continuing Resolution. This is about the same percentage as in the AFDC program, and we believe it to be an appropriate figure in the refugee program as part of our overall effort to hold down costs.

Both the figure for State administration and the figure for employment services reflect the lower number of refugee arrivals projected in the budget request.

In addition, we expect the service funds to be targeted more fully on employment-related services and on more recently arrived refugees.

Finally, prior years appropriations were unnaturally larger due to Continuing Resolutions; therefore, the reduction is much less and will result in more appropriation per capita amount for services.

Question. Will any States be forced to shut down their refugee programs?

Answer. No State has advised us that it will shut down its refugee program based either on our FY 1988 appropriation or on our FY 1989 budget request.

Question. What will prevent the State refugee program from simply providing income assistance, devoid of any components designed to develop self-sufficiency?

Answer. The FY 1989 request seeks funding for employment services and targeted assistance, both of which activities must concentrate on services to help refugees achieve employment.

Question. How much would be necessary in FY '89 to fund the social service program at the current level?

Answer. The FY 1988 appropriation for social services is $65,694,000. If current level means the same number of admissions and same policy as in FY 1988 then the amount required would be the same.

Question. According to the Department's budget justification, the President's fiscal year 1989 budget request for refugee and entrant assistance programs was based on the admission of 51,000 refugees. Does the Department continue to believe the admission figure of 51,000 is a realistic assessment for FY '89?

Answer. No, this number is a ceiling -- The maximum number of refugees that may be admitted in the fiscal year, we have observed that the actual number of arrivals has generally been lower than the ceiling . In its budget assumptions, the Department is still estimating an "expected value" of 51,000 refugees.

Question. If not, what is the Department's present estimate for refugee admissions in FY 89?

Answer. At the time we went to press, the Department estimate was 51,000 admissions; more recent data now estimates the number of admissions to be approximately 83,500.

Question. How much additional funding for the cash and medical and state administration accounts would be required to meet the increase in admissions?

Answer. In the event that the number of arrivals in FY 1989 should reach 68,500 - as reflected in the Department of State's budget request, an additional $17.6 million would be required to meet the expected increase in cash and medical assistance benefits and state administration costs.

Question. How much additional funding would be required to cover the increased admissions and restore cash and medical reimbursement to 31 months?

Answer. If, in addition to the assumed increase in admissions, the eligibility period for cash and medical benefits were to be raised to 31 months, total funding for cash and medical assistance and for State administration costs would require an estimated $51.2 million above the currently requested budget amount.

Question. What assumptions did you use in calculating the State administrative costs for the refugee cash and medical assistance programs in FY '88?

Answer. The FY 1988 budget request for funds for State administrative costs, was based on about 12 percent of the estimated cash and medical assistance costs, close to the percentage experienced in the AFDC program. The FY 1989 request would maintain that policy which was also adopted by Congress in the FY 1988 Continuing Resolution.

Question. Is it true that because of the special nature of the refugee program ORR encouraged states to provide case management services and allowed the states to charge this cost to the cash and medical assistance account?

Answer. Because Congress emphasized case management as a priority in the 1982 Amendments to the Refugee Act, we permitted States to claim types of case management costs against the combined grant for cash and medical assistance and State administration (CMA grant) as an aspect of State administration.

The types of case management activities which were allowed to be claimed against the CMA grant were those which were targeted to time-eligible cash/medical assistance recipients for the purpose of helping them to obtain or retain employment.

Question. Why did you propose additional state administration cost cuts in FY '89 when the case management services and costs have increased in the past three years and in FY '89 you reduced the social services budget by over 50%?

Answer. The FY 1989 budget request is based on a projected smaller number of refugee arrivals -- 51,000 -- as we have noted.

Question. I understand that a number of states have already spent their FY '88 allocation for state administrative costs because of the delayed notification of the reduction. What do you propose the states to do to continue the service delivery system?

Answer. The service delivery system is not solely or principally dependent on the availability of State administration funds since there is a separate FY 1988 appropriation of $65,694,000 for social services, most of which is being allocated to the States on the basis of a statutory formula.

## QUESTIONS SUBMITTED BY SENATOR ARLEN SPECTER

### AIDS - MINORITIES

Question. Many national and local Black and Hispanic organizations have had difficulty obtaining Federal AIDS education funds. What is the Department of Health and Human Services doing to ensure that minorities, who comprise 41% of the diagnosed AIDS cases, receive AIDS education funds?

Answer. $374.0 million will be spent on AIDS information and education in FY 1989. Information and Education programs directly for minorities increase from about $7.5 million in FY 1987 to $29.7 million in FY 1988 and $36.2 million in FY 1989. In addition to programs aimed directly at minorities, within the DHHS, PHS supports specific information and education programs aimed at the general public and at high risk populations. These programs increase from $152.3 million in FY 1987 to $333.7 million in FY 1988 and $447.0 million in FY 1989. See table on following page.

## PUBLIC HEALTH SERVICE

## AIDS-Information and Education Programs Indirectly Benefitting Minorities

| | 1987 | 1988 | 1989 | Estimated % of Funds Benefit. Minor. |
|---|---|---|---|---|
| CDC | | | | |
| Expand National Public Information Campaign including design and develop special programs for minorities........... | $13,692 | $7,831 | $10,140 | 20% |
| Every Household Mailer | --- | 15,000 | --- | |
| Assistance to States and Communities for conducting local public information efforts................. | --- | 7,500 | 15,000 | >20% |
| Counselng and Testing | 26,039 | 72,165 | 102,376 | 40% |
| Health Education/Risk Reduction State Prevention projects..... | 21,454 | 21,197 | 28,492 | 30% |
| School Health Activities | 11,076 | 29,916 | 36,450 | 20% |
| ADAMHA | | | | |
| NIDA - Information and Education aimed at high risk and infected 1/.... | 16,996 | 55,685 | 59,048 | 63% |
| NIDA - IV Drug Abuser Treatment and Demo. Activities 1/........... | --- | --- | 40,000 | 63% |
| NIMH - Publications..... | 139 | 837 | 1,560 | 15% |
| NIMH - Hlth. Care Wrkers. | 1,981 | 4,180 | 5,372 | 10% |
| Total, Information and Education........ | $91,377 | $214,311 | $298,438 | |

1/ It is estimated that 63 percent of the IV drug abusers are minorities.

Question. On November 17, 1987, I introduced S.1872, the "Minority AIDS Awareness and Prevention Projects Act." This bill provides $190 million over three years to national and local minority groups for AIDS outreach, education, prevention, counseling and research activities. These funds would be channeled through the Office of Minority Health, to ensure that minority groups receive funds swiftly and directly. A similar approach has been included in S.1220, passed by the Senate on April 28, 1988. Do you support such an approach?

Answer. We strongly support Congressional intent to ensure that national community-based minority organizations receive funds swiftly to assist in AIDS outreach education, prevention, counseling and research activities. For example, the Centers for Disease Control (CDC), through its surveillance and prevention cooperative agreements, is currently supporting through State and local public health departments more than 120 community organizations that serve or represent minorities. In this program, the funds are awarded to State or selected local health agencies with amounts earmarked not only to support special initiatives to prevent HIV infection among minorities, but also as a pass through for local minority organizations. We believe this approach helps assure needed coordination of AIDS prevention activities and it strengthens ties between official health agencies and the minority communities. Also more than 30 community-based organizations serving or representing minorities are being supported through a cooperative agreement with the U.S. Conference of Mayors.

As an added advantage of our approach the programs have the benefit of being backed up by the personnel and financial resources of CDC which is the lead agency in the Public Health Service (PHS) for preventing the spread of HIV infection through information, education, and risk reduction efforts. As a general organizing principal in PHS, we believe that the implementation of the public health programs should be the responsibility of the operation PHS agencies. Components of my office, such as the Office of Minority Health (OMH), are primarily staff offices whose function is to run pilot and innovative programs, stimulate program development as necessary, provide advice and assistance to me and the operating PHS agencies. Also, the OMH in its coordinative and advocacy role for minority health concerns has been able to influence the operating PHS agencies toward minority health priorities. Such a role is important to me and is just as effective as if OMH were to serve as an operating agency.

### AIDS - DRUG ABUSERS

Question. What steps will the Department take to expand the nation's treatment capacity for drug abusers, and more specifically for IV drug abusers, as recommended by the President's AIDS Commission?

Answer. The President's budget for FY 1989, which was developed before the recommendation of the AIDS Commission was delivered, contains $402 million in funds to States for drug abuse treatment, an increase of over 20 percent over the FY 1988 level. This increase, which is much higher than the general level of increases provided in the Department's budget, reflects the importance we have placed on expanding drug abuse treatment.

The Department is currently reviewing the recommendations of the AIDS Commission. While we have disagreements with some of the recommendations, in general we support the primary thrust of the report. As you know, the report mentions a number of objectives, but does not discuss the "nuts and bolts" of how to put such a plan in place.

## DRUG ABUSE TREATMENT

Question. According to the National Institute on Drug Abuse, there are 6.5 million persons seriously abusing drugs. It is projected that only 250,000 individuals are in treatment at any given time. The Department's FY 1989 request for drug activities is $596 million. Why are the Department's drug treatment and rehabilitation efforts lagging so far behind the obvious need for expansion of treatment services?

Answer. The FY 1989 budget contains a 20 percent increase in funds to States that can be sued for drug abuse treatment. This is a far larger increase than allowed in most accounts within the Department. At a time when many in this nation are greatly concerned about reducing Federal spending, I believe this demonstrates just how concerned we are with expanding the availability of drug abuse treatment.

## HEALTH STATUS OF MINORITY POPULATIONS

Question. What has the Department done to target funds and implement programs to improve the health status of minority populations in accordance with the 1985 recommendations issued by the HHS Task Force on Black and Minority Health?

Answer. In FY 1987, as the first step in carrying out its mission, the Office of Minority health (OMH) developed and issued guidance to DHHS agencies entitled, "Minority Health: HHS-Wide Program Coordination Process and Goals for the Year 2000", and thereby established the Health Issues Working Groups (HIWGs) as the mechanism through which OMH coordinates the minority health-related activities of the agencies within the Department. Specifically through the use of nine working groups, this process is an effort to (1) examine the gaps and needs in the six diseases and the three problem areas, (access and financing of health care, health data, and manpower issues) identified in the Task Force Report and (2) develop a coordinated strategic plan with measurable short and long range goals and objectives.

Each working group is charged with the responsibility of examining its disease or problem area in detail with a view towards reviewing current program strategies with respect to minorities. The Health Issues Working Groups (HIWGs) will complete a four phase process which is expected to increase the impact of existing programs on minority health. These four phases are:

- o Phase I - Systematic Program Assessment
- o Phase II - Goal Formation
- o Phase III - Development of the Minority Health Strategic Plan; and
- o Phase IV - Implementation of the Strategic Plan

Currently, the nine Health Issues Working Groups are completing Phase I - Systematic Program Assessment which consists of four tasks necessary to develop program review of minority health issues in DHHS. These tasks include: (1) an inventory of DHHS programs, (2) consolidation and integration of results, (3) an assessment of baseline data on programs, gaps and overlaps within DHHS, and (4) an evaluation to determine unmet needs in minority health. In response to Congressional request, OMH submitted in "draft" the assessment of the program reviews of the six priority diseases.

Specific projects and annual funding goals will be developed during Phase III - Development of the Minority Health Strategic plan. The plan will identify priorities and strategies for achieving the short-range, medium-range, and long-range goals. Priorities will be based on the severity of the need for improvement of minority health in specific disease or cross-cutting areas where disparities with the majority population are most acute. The Strategic Plan will establish priorities for the objectives and goals within the eight general areas of recommendations of the Secretary's Task Force Report and will discuss broad strategies the Department can pursue for influencing trends and developments in minority health.

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## QUESTIONS SUBMITTED BY SENATOR BARBARA A. MIKULSKI

### DRUG TESTING

Question. Your drug testing guidelines require a site collection person to administer and monitor drug tests. What are the minimal qualifications needed to be a collection site person?

Answer. The minimum qualifications of the site collection person are: same gender as employee, ability to read instructions, verify picture ID of employee, prepare the site collection room, order and handle supplies, handle security of specimens, prepare for shipment, and respond to questions on procedures asked by employee.

Question. Will background checks be conducted of these prospective collection site persons before they are hired? By whom? How will you guarantee uniform standards for all agencies in hiring these individuals?

Answer. Over 22 agencies have indicated they will purchase collection services from a contract to be awarded by DHHS/NIDA. The contractor will be responsible for hiring staff and implementing a drug testing program for its own staff as a condition of award.

Question. What kind of training will these collection persons receive?

Answer. Contractors which provide collection services will be responsible for training their employees. The National Institute on Drug Abuse, Office of Workplace Initiatives is developing a Handbook on Collection Services to use as guidance for the agencies' Drug Program Coordinators. Based on the training need in the agencies, NIDA will be in a position to develop a formal response and will collaborate with OPM on making this training.

Question. The guidelines provide that certain kinds of employee behavior can require a collection site person to require the giving of a second urine sample under direct observation. Can you explain the specific kinds of employee behavior that would trigger this? How do you intend to guarantee that this standard is applied fairly and uniformly?

Answer. The collection site person may only have the employee provide a sample under direct observation if, as stated in the Mandatory Guidelines for Federal Workplace Drug Testing Programs at Subpart B.2.2(23):

> A higher level supervisor shall review and concur in advance with any decision by a collection site person to obtain a specimen under the direct observation of a same gender collection site person based on a reason to believe that the individual may alter or substitute the specimen to be provided.

In addition, the individual with the authority to authorize collection under direct observation is specified in each agency's Drug-Free Workplace Plan.

Question. The guidelines do not require sample splitting, where only half of an employee's urine sample is sent to a lab and the other half stored as a means for an employee to challenge a false positive test. What are the costs attributable to sample splitting?

Answer. The costs attributable to sample splitting will vary considerably depending on the number of specimens to be split, labeled, stored, inventoried, etc. The logistics of storing specimens in a secure area in a locked, frozen state, could be considerable.

Question. Why do the guidelines not require a lab to retest specimens when an administrative error in the testing procedure is detected?

Answer. The Mandatory Guidelines state at Subpart B.2.5(5) that:

> Should a false positive error occur on a blind performance test specimen and the error is determined to be an administrative error (clerical, sample mixup, etc.), the Secretary shall require the laboratory to take corrective action to minimize the

> occurrence of the particular error in the future; and, if there is reason to believe the error could have been systematic, the Secretary may also require review and reanalysis of previously run specimens.

Question. Why don't the guidelines require that employees and incumbent unions be notified of systematic administrative error or an error in technical analysis of specimens?

Answer. The Mandatory Guidelines state in the Preamble, at Response to Comments #34:

> Several commentors requested corrective action and reanalysis of previously run specimens in the case of discovered laboratory administrative error. They also requested that the union and all employees who tested positive be notified of the error in writing. The recommendation was to notify all employees with positive results who were tested between the time of resolution of the error and the preceding cycle of correct results. In the case of an administrative error, there are no plans to automatically have all specimens retested. The decision on whether to retest will be dependent on the type and extend of the error. For example, if a single employee's test results were transcribed incorrectly, nothing would be gained from rerunning all the specimens in a given timeframe since it would not change the values attributed to the specimens. If an error occurred such that it was not clear whose specimen was being tested and which results belonged to which specimen, this would require retesting of the group for which the values where uncertain and for those analyses for which the values were uncertain. However, it would be unproductive to require the automatic retesting of all specimens for any error.
>
> Agency policy under which individuals are notified of errors will depend on the circumstances. If the error is corrected before the results are reported to any employee, it is unnecessary to notify each employee that an error was discovered and subsequently corrected. If a discovered error affects an employee after results have been reported, the Medical Review Officer will be notified and the affected employee will also be notified through the appropriate mechanisms established by each agency.

Question. The guidelines permit, but do not require, agencies to conduct a minimum number of unannounced laboratory inspections. Why don't you require this? If a lab knows when an agency is coming to inspect, won't it be easier for them to cover up problems there? If we're going to have random employee drug tests, why shouldn't we have random testing of labs?

Answer. The requirements of the Mandatory Guidelines to maintain all data in hard copy form makes it extremely difficult to "cover up" problems. The inspection team will have access to all data generated on Federal employee samples. Continuous "random testing of labs" is provided in the Guidelines by the blind quality control samples submitted by the Federal agencies contracting with each laboratory.

Further, in the Mandatory Guidelines state in the Preamble, at Response to Comments #36:

> Several commentors indicated that laboratory inspections should be conducted unannounced and that union representatives should be permitted to accompany the inspection teams. The Guidelines neither require nor prohibit unannounced inspections. They contemplate that agencies will, through their contract with a certified laboratory, specify the terms and conditions of inspections in accordance with the requirements in the Guidelines. If individuals other than members of the inspection team were entitled to accompany the inspectors, it would significantly complicate coordination and conduct of the inspections. More importantly, we see additional participants in the inspection as inhibiting the laboratory's freedom to provide complete cooperation out of concern for protecting proprietary information. While some laboratories may be willing to provide escorted tours to union officials to illustrate the quality of their processes, the Guidelines do not establish a right for union officials to participate in inspections incident to certification of laboratories under these Guidelines (2.4(1)and 3.20).

Question. You rejected federal employee unions request to permit union representatives to be present during lab inspections because it would "significantly complicate" the inspection process. Why do you think this would complicate things, particularly when certain collective bargaining agreements in the private sector permit union officials to participate in such lab inspections?

Answer. The Mandatory Guidelines state in the Preamble, at Response to Comments #36:

> If individuals other than members of the inspection team were entitled to accompany the inspectors, it would significantly complicate coordination and conduct of the inspections. More importantly, we see additional participants in the inspection as inhibiting the laboratory's freedom to provide complete cooperation out of concern for protecting proprietary information. While some laboratories may be willing to provide escorted tours to union officials to illustrate the quality of their processes, the Guidelines do not establish a right for union officials to participate in inspections incident to certification of laboratories under these Guidelines (2.4(1) and 3.20).

## OFFICE OF THE INSPECTOR GENERAL

## STATEMENT OF RICHARD P. KUSSEROW, INSPECTOR GENERAL

ACCOMPANIED BY:

DENNIS P. WILLIAMS, DEPUTY ASSISTANT SECRETARY FOR BUDGET
SHIRLEY C. CAROZZA, DIRECTOR, DIVISION OF OS BUDGET SERVICES

### BUDGET REQUEST

Senator CHILES. Our next witness is Mr. Richard Kusserow, the inspector general for the Department of Health and Human Services. Mr. Kusserow has served in this capacity since June 1981.

The Office of the Inspector General is responsible for audits, investigations, and program evaluations of the Department's several programs which represent a total budget of $361 billion.

Mr. KUSSEROW. Thank you, Mr. Chairman.

For the sake of time, if I could, I will submit my formal testimony for the record.

Senator CHILES. Thank you, sir. It will be admitted in full in the record.

Mr. KUSSEROW. Then I can just highlight a few points.

We are requesting $86,430,000 in obligational authority, of which $40 million would come from the trust funds, where we would have to dedicate resources supporting those activities in the Medicare and Social Security Programs. We are proposing 1,302 FTE's for 1989.

This is our eighth time we have appeared before this committee to make a presentation of the work of the Office of the Inspector General. During that period of time, we have had roughly a 63-percent increase in the outlays of the Department, increasing about $154 billion or an average of slightly less than $20 billion a year.

### PREPARED STATEMENT

During that same period of time, we have had OIG's overall staffing levels reduced by 6 percent. Notwithstanding that, we have been able to hold our own fairly well. Successful prosecutions have increased by 700 percent during that period of time, going from 165 in 1981 to roughly 1,200 this year.

[The statement follows:]

## STATEMENT OF RICHARD P. KUSSEROW

I am pleased to appear today to present the FY 1989 appropriation request for the Office of Inspector General. For FY 1989, I recommend $86,430,000 in obligational authority, of which $46,430,000 would be from FY 1989 appropriations. The balance of $40,000,000 would be transferred from the Social Security and Medicare trust funds to be used in direct support of those programs. Our budget request also provides for 1,302 FTEs in FY 1989. At these resource levels, the Office of Inspector General can continue to carry out its statutory responsibilities, including new sanction authorities added in 1985 and 1986, to protect the integrity of the Department's programs as well as the health and welfare of beneficiaries served by those programs.

In past years we decreased our staffing level in order to do our part to reduce expenditures and make the Federal workforce more efficient. A high degree of efficiency accompanied by increased productivity has been achieved through these efforts. However, expenditures of the programs we oversee have increased by nearly $100 billion over the last 5 years and have severely strained and stretched our ability to meet the increased workload. Also, in recent years, Congress has added many new responsibilities with the passage of 44 new sanctions authorities to protect beneficiaries and programs of the Department. New and increased audit requirements have also been added.

During the five year period from FY 1983 to FY 1988, DHHS program expenditures increased by 39 percent while our staff was reduced by ten percent. Despite this reduction, our productivity increased and we improved our ability to detect and prevent fraud, waste and abuse. In fact, our accomplishments have increased during each year that we reduced staffing. In FY 1987 our investigations resulted in 1,175 successful prosecutions, an increase of 700 percent over FY 1981 level of 165. In addition, we increased by 1,100 percent sanctions taken against health providers who abuse patients and programs. Our most significant contribution was monetary. We increased savings, recoveries, fines and settlements 3,300 percent during the period.

Funding in the OIG budget has been a good investment. Last year, an investment of $1 million resulted in $75 million in documented savings to the Department. The same $1 million investment produced 16 judicial and 6 administrative successful prosecutions against those found defrauding or abusing the Department's programs or beneficiaries.

Because of a carefully-managed productivity improvement program established 7 years ago, we have been able to increase the return on that investment in every year since 1981. Seven years ago the return on every $1 million that the Congress invested in the OIG budget yielded less than $5 million in recoveries, fines, settlements and other savings. Last year, that return on investment had risen to $75 million for each $1 million of your investment.

We will continue to provide a favorable return on investment in FY 1989 and future years for the Congress, the Department and the taxpayer. To do this, we will require some adjustments in the FY 1989 budget.

Perhaps most important, we will require an increase of 66 FTEs for FY 1989. These additional staff are needed to help us: implement the 27 new sanctions authorities enacted in 1985 and 1986; reduce the backlog of audit work resulting from the increases in funding of the Department's programs; respond to increasing Congressional demands for improved financial management and accountability through enactment of such laws as the Federal Manager's Financial Integrity Act; and address the increasing number of requests for studies and inspections we are receiving from Members of Congress and Departmental officials.

In addition, OIG will focus the staffing on high priority issues of concern to the Congress, the Department and the general public, including: reviewing systems to protect the safety of AIDS researchers and ensuring that the hundreds of millions of research dollars being invested in this area are being used for the purposes intended by the Congress; and monitoring and enforcing implementation of immigration reform efforts as they relate to use of Social Security numbers and the integrity of the Social Security System.

Because of growth in recent years in Federal health care expenditures and the proliferation of new medical technologies, therapies and products over the past few years, the Congress has enacted several new sanction authorities to protect beneficiaries and the financial integrity of the Medicare and Medicaid programs. We are very pleased with the passage in COBRA, 1985 and OBRA, 1986 of the new authorities to combat fraud and abuse in the social and healthcare programs. We appreciate the confidence the Congress has placed in us in developing these new enforcement tools. To date, no resources have been made available to fund this new effort. Thus, we have proposed for FY 1989 a minimum amount of increase in staffing and money to enable us to carry out those new responsibilities in a manner intended by the Congress. To meet this challenge, the FY 1989 budget request proposes new staff that will be equipped with computer skills and expertise in the healthcare field. In addition, our budget includes $200,000 to provide necessary training to our existing staff to enable them to carry out the new laws and keep pace with the new technologies.

Similarly, as the auditor for all of the Department's programs, our audit responsibilities have grown rapidly in the face of increased Departmental funding, which has averaged a growth of $20 billion per year in recent years. In addition to the audit responsibilities for the HHS, we are also the sole cognizant auditor for the entire Federal government at virtually all of the nation's colleges and universities, which includes 2,800 schools. Departmental funding of colleges and universities, as well as for State and local governments, has grown so large that we require the services of contract auditors to ensure the appropriate use of Federal funds. By using these contract auditors, under GAO audit standards and close OIG supervision, we free up OIG staff to work on more complex programmatic activities designed to identify and remedy systems vulnerabilities to fraud, abuse and waste. There is currently an enormous backlog of work growing in this area. We had begun to address this backlog in our FY 1988 budget request, but this was lost as result of the Budget Summit agreement. Our FY 1989 budget provides the additional funds to begin reducing some of the backlog.

In addition, our inspections activities have increased, with most of our inspections and evaluations in our FY 1988-1989 work plan in direct response to requested needs of Congress and Departmental policy makers. Our FY 1989 budget request would be used in part to increase our capacity in response to these growing demands.

The budget we are presenting today allows us to: (1) meet the challenge of providing greater protection for the health and the welfare of millions of beneficiaries served by those programs; (2) maintain our record of productivity gains; and (3) increase the financial integrity of the HHS programs. To do that we are proposing not only the additional FTEs described earlier on pages 99 to 102 of the budget justification, but also $1.9 million for expert contract medical services and university audit contracts. We need the services of contract medical experts to effectively implement our sanctions authorities, to provide consultations on some of the increasingly complex medical cases being uncovered by our investigators and to provide expert medical advice on complex quality of care issues under review in our inspections and audits. In the areas of appropriateness and quality of medical care, our ability to protect beneficiaries and the health financing programs is frequently directly tied to the availability of highly trained medical specialists.

Additional contract audit assistance will enable us to fulfill our responsibilities for audits of Federal funds at the nation's universities and colleges and State and local governments. This work covers not only funding from HHS programs but from other Federal agencies as well and is essential to insuring that Federal funds are used for their intended purposes.

In summary, the record shows that the Office of Inspector General has been a good investment for the Congress, the Department and the taxpayer during the last seven years. However, for FY 1989 we face new challenges. The Congress has enacted over 40 new legislative provisions that we are required to enforce. Medical technology has advanced dramatically, requiring us to have specially-trained professional staff to monitor the healthcare industry. We face a growing backlog of university and State and local government audits. To meet these challenges, we have developed a carefully-constructed management and resource plan. That plan is explained beginning on page 96 of our budget justification. I believe that the $86.4 million and 1302 FTEs we propose for FY 1989 will carry out that plan, continue our record of statistical accomplishments and provide better protection for the Department's program and beneficiaries.

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## BIOGRAPHY OF RICHARD P. KUSSEROW

Richard P. Kusserow was nominated as inspector general of the Department of Health and Human Services by President Reagan in April of 1981 and confirmed by the Senate in June.

As inspector general of the Department of Health and Human Services, he is charged with the statutory responsibility to ferret out fraud, waste, abuse and inefficiency in the world's largest agency. This department has some 250 health and human services programs and a budget of $361 billion which represents one-third of the federal budget.

Kusserow directs a staff of 1,300 auditors, inspectors, program analysts and investigators who recorded $5.3 billion in fines, savings, restitutions, recoveries and settlements in the last year. This represents a 3,000 percent increase over 1981 levels. More than $20 billion in such savings have been realized during Kusserow's tenure. In the same time frame, convictions resulting from his investigative staff rose from 165 to 1,200, a 700 percent increase. Additionally, he has increased administrative sanctions in excess of 1,000 percent against health providers and suppliers. He has "kicked out" of the Medicare and Medicaid programs nearly 2,000 individuals and entities for abusive or fraudulent behavior against the programs or beneficiaries.

Kusserow is currently serving a second term as the vice chairman of the President's Council on Integrity and Efficiency (PCIE). The PCIE, created in 1981 by President Reagan, provides cohesive leadership to governmentwide activities to reduce fraud, waste and abuse in federal programs and operations. Kusserow has responsibility for coordinating and tracking all governmentwide inspector general projects; managing the preparation of the President's semiannual report on the accumulated accomplishments of all inspectors general; coordinating efforts with the President's Council on Management Improvement; and, serving as liaison for all inspectors general with the Office of Management and Budget.

He earned his bachelor's degree from UCLA, followed by postgraduate work at Southern Methodist University and John Marshall University Schools of Law. He took a master's degree from California State University at Los Angeles.

Kusserow served in the United States Marine Corps and was discharged as a captain. He was an intelligence officer with the Central Intelligence Agency (CIA) before moving to the Federal Bureau of Investigation (FBI) in 1969.

As an FBI agent, he worked in Pennsylvania, Washington, D.C., West Virginia and Chicago. He acted as the coordinating supervisor for nine squads of agents constituting the Chicago FBI Organized Crime program preceding his appointment as inspector general.

Currently serves as president of the Baltimore Chapter of the Association of Government Accountants. On July 1, 1987, received the National Distinguished Leadership Award for sustained outstanding leadership and notable contributions in the field of financial management from the National Association of Government Accountants. He was twice elected national president of the Association of Federal Investigators and is an active member of the Society of Former FBI Agents, International Association of Chiefs of Police and the American Society of Industrial Security. He has lectured widely and authored numerous articles on innovative investigative and management techniques on fraud and corruption in government programs. He is author of a book entitled "Management Principles for Asset Protection."

### ADEQUACY OF FUNDING

Senator CHILES. Do you have enough money to do your job?

Mr. KUSSEROW. Well, I will do it with what you give me. We think that we have made a lot of progress with the work that we have done.

The question comes, though, Mr. Chairman, during the same period of time there have been a number of new responsibilities placed on our office in addition to the increasing responsibility that we have with the burgeoning budget.

And it is for that reason that we do need additional resources. This is the first time I have come before you to say that we need increases if we are going to meet some of the new obligations, particularly the rising number of sanction authorities that Congress is assigning to us to handle for the Department, as well as the increase in audit and related workload backlogs in the research community, especially the universities, where we have cognizant audit responsibility for some 96 percent of all colleges and universities in the country that receive Federal funds.

So to answer your question, we are doing a good job. We are doing as good a job——

### NEED FOR ADDITIONAL FUNDS

Senator CHILES. If you get the new money that is set forth, the $12 million, is that sufficient?

Mr. KUSSEROW. Probably not, but I am afraid I have to make a confession now. I am cursed as being a Presbyterian, which means coursing through my soul are the Scottish ancestors of the church, and it seems to me I have an obligation to demonstrate that I can make the best possible use of the funds that you appropriate for us.

Senator CHILES. Well, I am a Presbyterian, too, but I do not know anything that keeps a Presbyterian from telling another one a direct answer to his question.

Mr. KUSSEROW. The direct answer is that it is probably not sufficient, that probably within the next 2 years we are going to have to come back and ask you for more if you expect us to carry out the additional responsibilities that Congress is assigning to us.

### FUNCTION OF THE INSPECTOR GENERAL

Senator CHILES. Well, I think—you know, I want to make this clear. I believe that there was a strong, strong commitment in Congress to set forth the inspector general. We knew what we were doing. We put you in there in a way kind of like a bastard at a family reunion, because you are appointed by the President, you report to the President and the Congress.

We have engrafted you in on a system, and because of that we are not expecting you to say, I have got to live within the existing funds. You know, you do get a chance to ask directly and tell us what your budget should be. We expect you to do that.

And we are asking you to oversee all of these billions of dollars that we put out there, and we want that job done.

Mr. KUSSEROW. Thank you, Mr. Chairman. And we have long appreciated the fact that you are one of the original sponsors of the very first statutory inspectors general's offices created in the Federal Government, the office that I now hold, and your ongoing commitment to that.

Senator CHILES. And I think it is one of the better things that we did in the Congress, to set that up.

Mr. KUSSEROW. Thank you. I would imagine, though, there are a few folks from the Department behind me right now that probably still consider our office to be the bastard child at the reunion.

It seems to me with the phasing in of the new sanction authorities that have come down from the Congress, this Congress, that in the coming years we are going to have to come back to you and say: If you want the sanction effort to continue to police those programs the way that you have asked for, we are going to have to probably come next year and the year after to ask for increases as well.

The conflict I think that I have is that it is difficult in a period of great budgetary constraint, and during a period of time when hard decisions are made about program dollars, to look at oversight money and say we want a lot more when others are being cut back.

For that reason, I have been fairly restrained in the seven previous appearances before this committee.

Senator CHILES. I understand that. But when it comes to policing fraud and whether it is Medicare providers or who it is, hospitals, some doctors that are bad eggs, as there are some people that are bad in any profession or any group, we do not want to chintz on the ability to try to catch those people and for everybody to know that you are there to catch them.

Mr. KUSSEROW. Well, we feel that we still represent a pretty good bargain for the taxpayer, as well as for the beneficiaries, because the program that we have is designed to protect the interests of both.

In the dollar categories, the fines, savings, restitutions, settlements for the Department's programs, we went from $166 million in 1981 to $5.4 billion this last year, which is roughly a 3,500-percent increase in output. So we are pretty pleased about that.

As to what the appropriate level should be, it is hard for me to say. I would like some day to come before this committee and say that I would like to announce that we are reducing or we had a lower dollar return, we had fewer convictions, fewer sanctions, because we are winning the war.

Unfortunately, thus far I have not been able to declare victory or even say that I see the light at the end of the proverbial tunnel.

## MEDICARE PROGRAM SANCTIONS

Senator CHILES. Speaking of sanctions, the Medicare peer review organizations, they can recommend sanctions against doctors accused of providing substandard medical care. The only financial punishment is forfeiture of the fees for the case in question.

Do you think the sanctions are effective in eliminating doctors practicing substandard medicine from the Medicare Program? Do you have any recommendations on how we could improve this program?

Mr. KUSSEROW. It is not effective currently, and yes, I do have recommendations. One of the problems that we have in enforcing that provision has been the added statutory language that we must demonstrate that they are unwilling or unable to practice medicine.

That is undefined in the law. We have not been able to define it. It is a source of great contention if you want to exclude them.

Therefore, we are being forced to rely upon the provision that you offer, and that is that you can deny them their fee. It is sort of like issuing a traffic ticket, and yet human life is at stake.

We believe that what is needed is to have monetary penalties that are consistent with other actions of the Congress in trying to protect beneficiaries over the last few years, and raise that penalty up to maybe $10,000 or higher per case as an alternative to excluding a physician from practicing in the Medicare/Medicaid Program where their past behavior has been substandard.

We think in that way it would provide a range of alternatives that are not available now. So I think the program——

Senator CHILES. What you are saying is in many instances they are not going to be disbarred, so we ought to be able to levy some kind of fine?

Mr. KUSSEROW. That is correct, that the whole process is set up now so it is increasingly difficult to take action against them in terms of showing that they were gross and flagrant, and that they represent a threat to patients and therefore they should not be in the Medicare Program.

We think that there needs to be something in between, especially in rural areas where they may be the only physician in the community, to gain their attention and to make them more willing to pay attention.

And going back to the previous discussion you had with the Secretary about the fact that, if there are advances in biomedical research, that the benefits of those biomedical advances should be passed on to the patient. And in many cases that is not being done, and physicians are unwilling to adapt to change.

## MEDICAL MALPRACTICE DATA BANK

Senator CHILES. If we can get the medical malpractice data bank funded, will you be able to use that and will you help us police with that?

Mr. KUSSEROW. We have a very important role in that. The sanction authority for that data bank is the inspector general.

Senator CHILES. Before I leave the other thing, give us your recommendations in writing.

Mr. KUSSEROW. Oh, I would be pleased to do that, Mr. Chairman.

[The information follows:]

Following are our recommendations to change the PRO sanction authorities. We would be happy to provide to the subcommittee our draft report entitled "The Utilization and Quality Control Peer Review Organization [PRO] Program: Sanction Activities."

Amend section 1156 of the Social Security Act to strengthen the monetary penalty as an effective alternative sanction by allowing an imposition of a monetary penalty of up to $10,000 per violation for substandard, unnecessary, or uneconomical care. Currently, the law provides that only the amount paid the physician or provider for rendering the care in question may be recouped as a penalty. This measure would ensure that the PRO's have a viable sanction measure short of exclusion available to them.

Amend the PRO sanction statute to provide that the failure of physicians or providers to comply with their patient care obligations under section 1156, in itself, constitutes a sufficient basis for sanctioning. Thus, OIG recommends deletion of the existing statutory criterion for sanctioning that physicians or providers must be shown to be unwilling or unable to comply substantially with their obligations to Medicare beneficiaires. This change would make the statute consistent with the earlier Professional Standards Review Organization [PSRO] statutory language and authority and address the confusion related to what constitutes unwilling or unable.

Redelegate to the Secretary the sole responsibility for determining the type and extent of sanctions to be imposed, following a PRO determination that the care in question is sanctionable. This would ensure greater nationwide consistency in the application of sanctions, while preserving the authority of the PRO's to make statewide medical determinations. It would also help to alleviate the PRO's inherent frustrations and conflicts in their concurrent roles as educators and enforcers by relieving them of the responsibility of making recommendations on the type and extent of sanctions to be imposed.

## DATA BANK

Senator CHILES. Yes.

Now to the medical.

Mr. KUSSEROW. On policing the program, yes, Congress felt that indeed, if you do set up a data bank to make sure that information about practitioners, especially those that are errant, is in fact communicated to entities, such as hospitals that employ them. Then, what are the enforcement mechanisms to make sure that reporting to the bank in fact occurs and confidentiality is protected. There are certain civil money penalty provisions in the law that we will enforce to address this question.

One of the provisions, incidentally, is to make sure that there is not a misuse of that data. And so we do have enforcement responsibility on that, and I pledge to you that we in fact will work there.

I would like to parenthetically add, Mr. Chairman, that this is one of some 44 new sanction authorities that Congress has expressed confidence in the Inspector General's Office to enforce. In none of the 44 new authorities has there been any funding, and that is one reason why——

## ACQUIRED IMMUNE DEFICIENCY SYNDROME

Senator CHILES. I understand, I understand.

In our AIDS funding, we are now increasing dramatically, from $479 million in 1987 to a projected $1.3 billion in 1989. Any time you increase funding in that kind of magnitude, there is a tremendous danger for waste or fraud or maybe both.

What is your office doing to try to make sure that the money is used for the purposes that Congress has designated it for?

Mr. KUSSEROW. Well, first let me just underscore your comments and say that we have never had to my knowledge in the history of this country any major crash program to solve a problem wherein there have not been attendant problems as a result of the expansion, causing vulnerability. So I quite agree with you that we have an obligation on several fronts in this crisis.

First of all, we want to be sure that the dollars are not going to be misspent and wasted away, that they in fact are going to be applied to looking for a solution to the AIDS problem.

Second, I think what we want is to be sure that there is quality research out there, that we are not going to be led up blind alleys by principal investigators at some university or on campus at NIH who might get overly aggressive in trying to make a name for themselves and thus through faulty research lead the whole community up blind alleys.

In connection with that, we have built this issue into our current workplan which, if you like, Mr. Chairman, I would be pleased to make available to the committee. We have some 600 projects in the workplan. Many of them involve putting our resources back into reviewing the university community, looking at what they are doing, and making sure that the grant research is done appropriately, and that the quality of the research effort is what it should be.

And we have in our 1989 budget a proposal to add $800,000 of effort into doing audits of projects awarded from NIH and other biomedical research arms of the Department to universities. We have already begun that process.

We are now looking at some research facilities that are grantees to see whether or not there is going to be a representative problem there.

Also, it seems to me that it is becoming increasingly clear that, although the Public Health Service does not have the largest part of the Department's budget, certainly the preponderant number of HHS programs are in PHS. Over the years, I have established separate audit divisions for the operating divisions of our Department. I have a social security audit director, I have a health care financing audit director.

I do not have a Public Health Service audit director who has a full-time staff devoted to servicing the Public Health Service. I have talked to Dr. Windom about that. We are in the process of establishing such a division. I intend to use current reallocated resources to that effort, and then also some of the new FTE's that hopefully are going to be added in our budget for 1989 will also be devoted to reinforcing that area.

We also are hopeful that we can work out a more efficient way in which we can have biomedical oversight. Currently at NIH, the investigation of allegations of scientific misconduct are on campus with the division of management survey and review, an audit group within, that reports to NIH.

I think that we should look at that. I have a problem in this respect, that many times the complaints that come in on biomedical misconduct are not exclusively at universities out into the hinterlands, but are also in intramural research within PHS itself.

And then it is sort of like the in-house group——

Senator CHILES. Looking at themselves.

Mr. KUSSEROW. Yes; that is right.

### NATIONAL INSTITUTES OF HEALTH PROCUREMENT SYSTEM

Senator CHILES. Well, I think you ought to look at that.

I have seen your April 15 letter to Secretary Bowen regarding the problems with the NIH procurement system. Earlier this week I talked to Dr. Wyngaarden. He assured the committee that remedial action has been taken.

Tell the committee, are you satisfied with the NIH response today?

Mr. KUSSEROW. I was never satisfied with the NIH response. That is why I went to the Secretary on this. I thought that NIH has had a despicable record in this area. It had 5 years of a series of a report from not only the Inspector General's Office, but from the Assistant Secretary for Health——

Senator CHILES. Well, in addition to going to the Secretary, I want you to come to this committee now and copy us with your findings and keep us up to date.

Mr. KUSSEROW. Anticipating you, Mr. Chairman, I did bring copies of that report, and I would be happy to give it to the committee today.

Senator CHILES. Fine, and especially the followup now, too, to see whether Dr. Wyngaarden is going to do what he told me he would do there, too.

Mr. KUSSEROW. Well, part of the Department's followup responsibility falls under Mr. McCann, who was previously testifying with the Secretary and is the Assistant Secretary for Management and Budget. Mr. McCann has already taken the action to pull back procurement authority from ORS and has already taken remedial steps.

So that is being done at the Secretary level.

Senator CHILES. All right, sir.

We thank you very much for your statement.

### SUBCOMMITTEE RECESS

Senator CHILES. We will recess now until the call of the Chair.

[Whereupon, at 1:45 p.m., Friday, April 29, the subcommittee was recessed, to reconvene at the call of the Chair.]

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